IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

GLENN GATES and DONNA GATES, h/w on behalf of themselves and all others similarly situated	: : :
Plaintiffs,	CLASS ACTION
V.	Civil Action No. 2:06-CV-01743-GP
ROHM AND HAAS COMPANY, et al.,	
Defendants.	· :
	DATE.
OR 	DER
This day of	, 2008, upon consideration of Defendants'
Omnibus Motion to Exclude Reports and Testin	nony by Plaintiffs' Experts, it is ORDERED that
the motion is GRANTED. For the reasons set for	forth in the record, plaintiffs are PRECLUDED
from offering the expert reports, opinions embo	died therein, or any evidence or testimony in sup-
port of the reports of the following witnesses: D	r. Charles Andrews, Mr. J. Gregory Hill, Dr.
Paolo Zannetti, Dr. June Ann Oberdorfer, Dr. G	ary Ginsberg, Dr. Sidney D. Finkelstein, and Dr.
Richard Neugebauer.	
	BY THE COURT:
	Pratter. J.

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Plaintiffs,

Civil Action No. 2:06-CV-01743-GP

ROHM AND HAAS COMPANY, et al.,

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Defendants.

DEFENDANTS' OMNIBUS MOTION TO EXCLUDE REPORTS AND TESTIMONY BY PLAINTIFFS' EXPERTS

For the reasons set forth in the accompanying memorandum and exhibits, defendants Rohm and Haas Company, Rohm and Haas Chemicals LLC, and Morton International Inc. move for an Order to exclude the expert reports, opinions, and testimony of the following experts proffered by plaintiffs in support of their motion for class certification: Dr. Charles Andrews and Mr. J. Gregory Hill; Drs. Paolo Zannetti and June Ann Oberdorfer; Dr. Gary Ginsberg; Dr. Sidney D. Finkelstein; and Dr. Richard Neugebauer.

/s/ Ralph G. Wellington

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Dated: January 28, 2008.

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

GLENN GATES and DONNA GATES, h/w : CLASS ACTION

On behalf of themselves and all others simi:

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Defendants.

BRIEF IN SUPPORT OF DEFENDANTS' OMNIBUS MOTION TO EXCLUDE REPORTS AND TESTIMONY BY PLAINTIFFS' EXPERTS

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Dated: January 28, 2008

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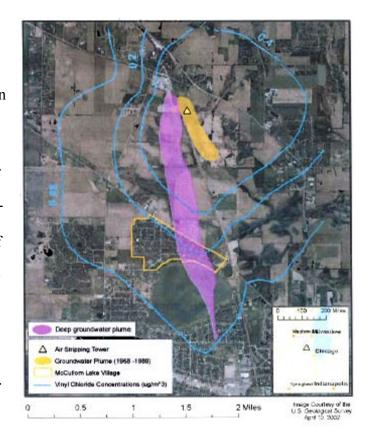
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I. INTRODUCTION

When plaintiffs filed their reply brief in support of their motion for class certification, they also filed new reports by several expert witnesses, who together set forth a new and completely revised theory of plaintiffs' case. Stated briefly, that new theory is that:

- (1) waste water containing chemicals was discharged into a lagoon/landfill at defendant Morton's facility, and the chemicals degraded to form vinyl chloride;
- (2) the vinyl chloride flowed underground in two "plumes" —

 (a) a shallow plume (depicted in orange on the map on page 21 of plaintiffs' reply brief, which is reproduced here) that emptied into a marshy area southeast of defendants' plant and more than a mile north of McCullom Lake Village, and (b) a deeper plume (the purple plume on plaintiffs' map) that flowed through an alleged underground channel into the eastern part of McCullom Lake Village, where it contaminated some Village drinking wells;



(3) between 1968 and 2002, the vinyl chloride allegedly evaporating from the shallow (orange) plume blew over the Village, where some Village residents breathed varying amounts of it;

- (4) between 1978 and 2002, vinyl chloride in Village wells above the deeper (purple) plume mixed with the air in some Village houses as the well water was used for household purposes, and residents of those houses breathed it;
- (5) breathing of the vinyl chloride placed Village residents at risk of contracting brain cancer;
- (6) the contamination had an adverse impact on the value of all real estate in the Village as of April 2006; and
- (7) Village residents are entitled to (a) have a program put in place to monitor for a brain cancer risk, and (b) damages for harm to the value of their properties as of April 2006.

This convoluted theory is not supported by the facts. It presents issues fundamentally different from those in a typical chemical exposure case, for plaintiffs here concede there is no evidence of current contamination by defendants in the putative class area. Plaintiffs' case hinges entirely on the opinions of plaintiffs' experts, which are based on speculations, theoretical modeling, and hypotheses as to historical facts that are contrary to the actual facts — and, in most cases, contrary to established science as well.

The evidence shows that vinyl chloride *never* has been found in Village wells. Indeed, borings right through the hypothesized purple plume show no evidence that vinyl chloride *ever* flowed or could have flowed along that supposed pathway into Village wells at all, and chemical "fingerprinting" of water found in the wells establishes that supposedly elevated levels of chloride in the Village (that's *chloride*, *not* vinyl chloride; again, vinyl chloride *never* has been found in any Village well) did not come from defendants' plant. The evidence also shows

that vinyl chloride has *never* been measured in Village air above background levels, and that it was impossible for levels of vinyl chloride to reach the levels in Village air that plaintiffs theorize. And beyond all that, the scientific evidence shows that there is no established link between vinyl chloride exposure and any risk of brain cancer.

This is not just a dispute about the evidence or a disagreement among scientists about how to apply scientific theories to the evidence. The dispute is much more fundamental: the theories, assumptions, and suppositions of plaintiffs' experts are so contrary to the facts and to science that they are not admissible under Rule 702 of the Federal Rules of Evidence and Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993). Normally, defendants would defer litigation of their Daubert objections until closer to trial. But the case is now at the class certification stage, and plaintiffs have presented their experts' theories not just to support their claims on the merits, but also (they say) to prove the elements they must establish to justify class certification under Civil Rule 23. Therefore, defendants move now for exclusion of the reports, the opinions they contain, and any testimony or other evidence that relates to them, insofar as this evidence relates to class certification. Plaintiffs' reliance on the expert evidence to prove class issues makes it necessary for the Court to determine the admissibility of this evidence at this time.

This motion applies to seven of plaintiffs' experts:

- Dr. Charles Andrews and Mr. J. Gregory Hill (plaintiffs' hydrogeology experts);
- Drs. Paolo Zannetti and June Ann Oberdorfer (plaintiffs' air emissions experts);
- Dr. Gary Ginsberg (plaintiffs' toxicologist);
- Dr. Sidney D. Finkelstein (plaintiffs' neuropathologist); and
- Dr. Richard Neugebauer (plaintiffs' epidemiologist).

Defendants recognize that a motion to exclude so many experts is unusual, and they do not make this motion lightly. But the fact is that all of the experts, and their reports, are presented together as a single package, with frequent cross-references between and among them and heavy reliance by each on the others. Their presentations strongly suggest that they began with a joint effort to come up with a preordained result favorable to plaintiffs, and that the witnesses then created and parceled out pieces of a theory designed to fit that result. For that reason, each of the expert reports should be excluded and defendants have filed this omnibus motion that addresses all of them.¹

II. THE APPLICABLE LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. It states:

If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

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^{1.} All documents cited in this brief are either exhibits to plaintiffs' class certification filings ("Pl. Repl. Br., Ex. ___"), defendants' opposition to plaintiffs' motion ("Def. Opp. Br., Ex. ___"), or are being filed with this brief as attachments to an affidavit by Jennifer A. L. Battle, Esquire. Reports of defendants' experts are attached as the first two volumes of that affidavit; the report of Dr. Robert Mutch comprises Volume I, and all other reports are in Volume II, arranged in alphabetical order. All excerpts from deposition transcripts are in Volume III, arranged in alphabetical order. Defendants' remaining exhibits are numbered and are in Volume IV.

Rule 702 codifies the direction of the Supreme Court in *Daubert* that a district court is to serve as a gatekeeper to ensure that evidence presented by a party's expert witness is relevant, reliable, and helpful to the jury. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999); *see also Elcock v. Kmart Corp.*, 233 F.3d 734, 744-45 (3d Cir. 2000); *Total Containment, Inc. v. Dayco Prods., Inc.*, 2001 U.S. Dist. LEXIS 15838, at *8-*10 (E.D. Pa. Sept. 6, 2001). This obligation applies not only to testimony based on "scientific" knowledge, but also to testimony based on "technical" and other "specialized" knowledge. *Kumho*, 526 U.S. at 149. The party seeking to introduce the expert testimony bears the burden of establishing its admissibility. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000), *cert. denied*, 532 U.S. 921 (2001).

Under Rule 702, admissibility of expert evidence depends on two inquiries. The first is whether the witness is qualified to testify "by knowledge, skill, experience, training, or education." Defendants do not challenge the qualifications of any of plaintiffs' experts at this time. Instead, this motion is addressed to the second inquiry under Rule 702: whether the witness' proposed testimony is reliable. The test for reliability is an "exacting" one. *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000). As codified by the 2000 amendments to Rule 702, it involves three distinct inquiries:

pends on the quality of the data the expert reviewed in forming his or her opinion. An opinion based on unreliable data should be excluded. *See*, *e.g.*, *In re Diet Drugs Prod. Liab. Lit.*, 2000 U.S. Dist. Lexis 9661 (E.D. Pa., June 28, 2000) (excluding opinions based on unreliable data, insofar as the results of *in vitro* studies could not be reliably extrapolated to humans). This was the law in this Circuit even before the Supreme Court's decision in *Daubert*. In *Advent Sys. Ltd.*

v. Unisys Corp., 925 F.2d 670, 682 (3d Cir. 1991), the Court of Appeals explained that "[a]lthough facts not otherwise admissible in evidence may form the basis for assumptions by an expert witness, the court must make a factual inquiry and finding as to what data experts in the field find reliable." As the Court observed, "[a]n opinion based on false assumptions is unhelpful in aiding the jury in its search for the truth, and is likely to mislead and confuse." Id. (quoting Wilkinson v. Rosenthal & Co., 712 F. Supp. 474, 479 (E.D. Pa. 1989)). See also Cummins v. Lyle Indus., 93 F.3d 362, 366-71 (7th Cir. 1996) (affirming district court decision to exclude expert testimony predicated on expert's own untested observations without reliance on scientific method); Tyger Constr Co. v. Pensacola Constr. Co., 29 F.3d 137, 143-45 (4th Cir. 1994), cert. denied, 513 U.S. 1080 (1995) (excluding expert testimony that was speculative and not supported by the record); Joy v. Bell Helicopter Textron, Inc., 999 F.2d 549, 568-69 (D.C. Cir. 1993) (excluding expert testimony "based solely on guesswork, speculation, and conjecture" in situation where court believed that "the decision to receive expert testimony was simply tosse[d] off to the jury under a 'let it all in' philosophy').

As a specific application of this principle, a court should exclude expert testimony where the expert "cherry picks" those facts that support his theory, and ignores those that do not. *See*, *e.g.*, *Barber v. United Airlines*, *Inc.*, 17 Fed. Appx. 433, 437 (7th Cir. 2001) ("selective use of facts fails to satisfy the scientific method and *Daubert*"); *Holden Metal & Aluminum Works*, *Ltd. v. Wismarq Corp.*, 2003 U.S. Dist. Lexis 5247 (N.D. Ill., Apr. 2, 2003) at *6 (expert opinion based on "cherry-picked" facts is inadmissible under *Daubert*).

2. Reliability of Principles and Methods. Even if the district court is satisfied that good factual grounds underlie an expert's opinion, it must still evaluate the expert's methodology. An expert's opinion "must be based on the 'methods and procedures of science'

rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994). *See Daubert*, 509 U.S. at 590; *Fedorczyk v. Caribbean Cruise Lines*, 82 F.3d 69, 75 (3d Cir. 1995); *Advent Sys.*, 925 F.2d at 682. The party proffering the expert testimony and opinion has the burden of establishing by the preponderance of the evidence the reliability of the principles and methods employed. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999).

There is no exhaustive list of the indicia of reliability the expert's methodology must satisfy, but relevant factors include:

- (1) "whether [the methodology] can be (and has been) tested";
- (2) "whether the theory or technique has been subjected to peer review and publication";
- (3) "the existence and maintenance of standards controlling the technique's operation"; and
- (4) whether the expert's methodology is generally accepted in the scientific community.

Daubert, 509 U.S. at 593-94. The Third Circuit has identified a more comprehensive list:

(a) whether a method exists of a testable hypothesis; (b) whether the method has been subjected to peer review; (c) the known or potential rate of error; (d) the existence and maintenance of standards controlling the technique's operation; (e) whether the method is generally accepted; (f) the relationship of the technique to methods established to be reliable; (g) the qualifications of the expert witness testifying based on the methodology; and (h) the non-judicial uses to which the method has been put. *Oddi*, 234 F.3d at 156, *citing Paoli*, 35 F.3d at 742 n.8. These factors

are non-exclusive and the approach to determining the admissibility of expert testimony is a flexible one. *Kumho*, 526 U.S. at 150-51; *Daubert*, 509 U.S. at 593-94. *See also Paoli*, 35 F.3d at 742 ("a district court should take into account all of the factors listed by *Daubert* . . . as well as any others that are relevant").

Although the Third Circuit has adopted a "flexible" test for reliability, the expert's opinion must, at a minimum, be based on some methodology or analysis that can be explained and tested. Elcock, 233 F.3d at 746-48, 754-56 (holding that because plaintiffs' expert "never explained his method in rigorous detail," it was "impossible" for defendant's experts to repeat his "apparently subjective methods" and his opinion was unreliable, and excluding testing by another expert whose testimony was not accompanied by a "sufficient factual foundation"). See also Oddi, 234 F.3d at 144-45 (a "key question" is whether the theory "can be (and has been) tested"); Kannankeril v. Terminix Int'l Inc., 128 F.3d 802, 806 (3d Cir. 1997) (the test of admissibility is whether the opinion "is based on valid reasoning and reliable methodology"); Murray v. Marina Dist. Dev. Co., LLC, 2006 U.S. Dist. LEXIS 92769, *11-*13 (E.D. Pa., Dec. 22, 2006) (expert opining as to propriety of security measures in casinos precluded because "(1) he did not cite to any established industry standard for his opinions on requisite necessities for adequate security, and (2) he did not provide any explanation that could be tested or subjected to peer review as to how he reached his opinions"); Bethea v. Bristol Lodge Corp., 2002 WL 31859434 at *5 (E.D. Pa., Dec. 18, 2002) ("[T]the expert must explain the means by which he reached his conclusions, and such means must satisfy at least one of the Daubert factors of reliability").

3. Reliable Application. Even if the underlying data and basic method are sound, the district court must still examine how they have been applied in the particular case and determine whether the expert's conclusions "reliably follow from the facts known to the expert

and the methodology used." *Schieber v. City of Philadelphia*, 2000 U.S. Dist. Lexis 17952, *8 (E.D. Pa., Dec. 13, 2000). The opinion must "logically advance[] a material aspect of the proposing party's case." *Daubert v. Merrrell Dow Pharmaceuticals, Inc.*, 43 F.3d at 1311, 1315 (9th Cir. 1995) (*Daubert II*), *cert. denied*, 516 U.S 869 (1995). Admissibility under this factor turns on "the proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case." *Oddi*, 234 F.3d at 145, *quoting Paoli*, 742 F.3d at 743. "This connection has been described as a 'fit' between the testimony offered and the facts of the case." *Oddi*, 234 F.3d at 145 n.12, *citing Daubert*, 509 U.S. at 591. If the Court concludes there is too great a gap between the data and the opinion offered, the Court should exclude the testimony. *Id.* at 146.

In this connection, the Court should consider the "the non-judicial uses to which the method has been put," *Paoli*, 35 F.3d at 742 n.8, because the expert must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho*, 526 U.S. at 152. The expert's opinions should not be admitted when "there is simply too great an analytical gap between the data and the opinion proffered." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

Moreover, the expert must hold his opinions to a "reasonable degree of scientific certainty." *Lanza v. Poretti*, 537 F. Supp. 777, 785 (E.D. Pa. 1982). Testimony concerning mere possibilities is "speculation and conjecture." *Id.* Unless the expert's testimony surpasses the threshold of reasonable certainty, "there is nothing on the record with which a factfinder can make a decision with sufficient certainty so as to make a legal judgment." *Paoli*, 35 F.3d at 751, *quoting Cohen v. Albert Einstein Med. Ctr.*, 592 A.2d 720, 723 (Pa. Super. Ct. 1991).

III. REASONS THE EXPERTS SHOULD BE EXCLUDED

The bases for excluding the reports and evidence of plaintiffs' experts are set forth in the following sections of this brief. There are many reasons, but here are some of the main ones:

- *Dr. Charles Andrews and Mr. J. Gregory Hill.* Dr. Andrews created a model to show that detectable levels of vinyl chloride from the Morton lagoon/landfill migrated into the residential Village wells through a deep aquifer (the purple plume) from 1978 until about 2002. Mr. Hill relies on Dr. Andrews to reach this same conclusion. However, instead of collecting the necessary field data upon which to construct a model, Dr. Andrews cherry picked limited available data, made unsubstantiated assumptions about it, and ignored well-accepted peer reviewed literature to reach an unsupportable result. Had Dr. Andrews collected the field data, as defendants have now done, he would have found that the data directly contradicted his model.
- Drs. Paulo Zannetti and June Ann Oberdorfer. Dr. Zannetti developed a series of models that purport to show levels of vinyl chloride that volatized (that is, evaporated) into the air from the plume north of the Village (the orange plume). The models are based on emission rates created by his colleague, Dr. Oberdorfer, on the basis of assumptions not supported by the record and that were admittedly designed to reach results higher than what the data shows. Indeed, Dr. Zannetti admits that his models are not based on the "best estimate" of the emission rates, but on a "higher estimate."
- *Dr. Gary Ginsberg*. Dr. Ginsberg's purported calculation of the vinyl chloride exposures in the class area is based on faulty formulas and flawed data borrowed from the air and water experts. And because vinyl chloride has not been shown to cause brain cancer, his risk

assessment likewise is the result of a convoluted manipulation of regulatory risk factors and rat studies, none of which follows accepted scientific principles or adequately accounts for individual factors.

- *Dr. Sidney D. Finkelstein*. Dr. Finkelstein developed a methodology solely for purposes of litigation to show chromosomal damage from vinyl chloride. He began by mimicking past scientific research, but then stopped without doing the actual work necessary to form a reliable scientific opinion. His opinion is not based on sufficient facts or data and is scientifically meaningless.
- *Dr. Richard Neugebauer*. Dr. Neugebauer likewise invented a methodology for this litigation in order to inflate his calculated brain cancer rate, but failed to apply his own methodology in a scientifically sound manner. Even if he had done everything right in making his calculations, his opinion would still say nothing more conclusive than that further study is needed to determine whether there actually is a higher-than-expected number of brain cancer cases in the Village.

A. DR. CHARLES ANDREWS AND MR. J. GREGORY HILL

1. BACKGROUND

When this lawsuit was filed, plaintiffs claimed they were exposed to vinyl chloride that had migrated into their residential wells in McCullom Lake Village from the disposal lagoon/landfill at the manufacturing facility in Ringwood, Illinois owned and operated by Morton International until 1999, and thereafter by Rohm and Haas. From the start, plaintiffs encountered fundamental fact problems with their theory. First, two rounds of testing conducted by plaintiffs of those residential wells failed to reveal the presence of any vinyl chloride. Second, extensive work by Morton and Rohm and Haas showed that any contaminants released into groundwater from the facility were in a plume that was traveling southeast from the facility — away from the residential wells of McCullom Lake Village.

Plaintiffs' first theory — known as the "mounding" theory — was proffered by J. Gregory Hill. Mr. Hill claimed that the force of the volume of wastewater released into Morton's lagoon/landfill would cause a "mounding" effect that pushed the groundwater out in all directions, eventually causing some contaminated groundwater to reach McCullom Lake Village's residential wells. Hill 2006 Report (Pl. Mo. for Class Certif., Ex. A) at 5-6. Mr. Hill explained the absence of detectable vinyl chloride in those residential wells today by saying that once the lagoon closed, the mounding effect ceased. *Id.* at 6. In response to criticisms by Rohm and Haas's hydrogeologist, Robert Mutch, plaintiffs' have now abandoned their mounding theory.

In January 2007, after defendants argued that plaintiffs' own testing showed there was no current contamination in the Village, plaintiffs sampled 22 residential wells in and

around the Village. *None* tested positive for vinyl chloride. Eight of those 22 wells had elevated levels of chloride (a different chemical)², that is, levels above background range.

So plaintiffs' newest hydrogeology expert, Dr. Charles Andrews, came up with a new theory. Dr. Andrews theorized that waste water from the Morton lagoon/landfill reached a deeper aquifer and then traveled in that deeper aquifer directly south to McCullom Lake Village. Dr. Andrews designed a groundwater model to reflect that hypothesis.

Models can be helpful in determining the flow of hazardous substances in groundwater. But groundwater models not based upon sound, accurate and adequate field data are of no value. Worse, they can mislead. Dr. Andrews' model is not based upon such data and is grossly misleading.

Dr. Andrews never collected any field data in the 1½ mile stretch between the Morton lagoon/landfill and McCullom Lake Village. Instead, with the skimpiest of available information, he plugged a series of assumptions into his model, each designed to help reach his foregone conclusion. In doing so, Dr. Andrews repeatedly (1) made unsupported and indefensible assumptions without collecting the necessary field data to determine if they were correct;

^{2.} Chloride and vinyl chloride are different things. Vinyl chloride is a man-made, colorless gas primarily used as an adhesive in manufacturing. C.C. Lee, ENVIRONMENTAL ENGINEERING DICTIONARY (2d ed. 1992). In contrast, chloride is a common substance that naturally occurs in body fluids. There are large amounts of it in the human body, and it is considered an essential constituent for life. Chloride is common in the environment because it is naturally occurring in many geologic formations, and because of its many uses by man, such as in road salt and septic systems. Valberg Aff. of Mar. 1, 2007 (Battle Aff., Vol. IV, tab 12) ¶¶ 11- 12. Indeed, chloride makes up 60% of ordinary table salt. *Id.* ¶ 8.

(2) cherry-picked the limited available field data, ignoring facts that contradicted his theory; and(3) ignored accepted peer-reviewed literature.

As explained below, Dr. Andrews had to make at least five assumptions in his model. Those assumptions are plainly inconsistent with the facts, based upon pure conjecture, or inconsistent with peer-reviewed hydrogeological literature. The errors in Dr. Andrews' model have been confirmed by field data collected and analyzed by Rohm and Haas's expert, Robert Mutch. Mr. Mutch oversaw installation of monitoring wells in the 1½ mile stretch between the Morton facility and McCullom Lake Village to determine the nature of the geologic material, define groundwater flow directions, and determine the groundwater characteristics. Mr. Mutch's data disproves each of Dr. Andrews' assumptions. Additionally, Mr. Mutch directed performance of a chemical fingerprinting analysis to compare the groundwater at the Morton facility with that in the residential wells of McCullom Lake Village. That analysis conclusively establishes that chloride in the Village wells did *not* come from the former Morton facility. The undeniable facts show that Dr. Andrews' model is clearly unreliable.

Where, as here, an expert opinion is contrary to the field data and peer-reviewed literature, the Court should exercise its "gatekeeper" responsibility under Rule 702 to exclude the testimony. And since Mr. Hill's opinion is admittedly based on Dr. Andrews' defective model, it too must be excluded.

2. ARGUMENT

THERE IS NO SUPPORT FOR THE ASSUMPTIONS IN DR. ANDREWS' UNRELIABLE GROUNDWATER MODEL

Dr. Andrews' groundwater model is premised upon at least five critical assumptions that are either unsupported by the facts or contrary to the facts.

a. FIRST UNFOUNDED ASSUMPTION: Contrary to Dr. Andrews' Hypothesis, There Is No Hypothetical Purple Plume.

From the beginning, plaintiffs have encountered fundamental factual problems with their theory of groundwater contamination. First of all, two rounds of testing by plaintiffs showed *no* evidence of vinyl chloride contamination in the wells of McCullom Lake Village. *See* Letter from J. Gregory Hill to A. Freiwald (Feb. 2, 2007) (Battle Aff., Vol. IV, tab 6). So plaintiffs switched their theory to focus on chloride found in seven McCullom Lake wells, which they claim can be traced back to the Morton facility. The biggest — and clearly wrong — assumption underlying Dr. Andrews' model is that chloride found in seven residential wells in McCullom Lake Village came from the Morton lagoon/landfill. *See* Andrews Report (Pl. Repl. Br., Ex. C-5) at 12.

Plaintiffs' experts say that while vinyl chloride will eventually volatize, making it no longer detectable in groundwater, chloride is much more soluble and will stay in groundwater for a longer period of time. Hill 2007 Report (Pl. Repl. Br., Ex. C) at 10; Hill Dep. at 202-03. Ergo, say Dr. Andrews and Mr. Hill, the presence of chloride in the residential wells at McCullom Lake Village supports their claim that Dr. Andrews' hypothetical purple plume once was present in those residential wells, to the exclusion of all other more likely sources. Hill 2007 Report at 10; Hill Dep. at 202-03; *see also* Andrews Dep. at 36-37. At the time Dr. Andrews'

model was prepared, there were no monitoring wells in the 1¼ mile stretch (more than 8,000 feet) between the Morton lagoon/landfill and McCullom Lake Village and, therefore, no field data to support Dr. Andrews' assumption.

When confronted with that absence of supporting field data, Dr. Andrews could say only there were elevated levels of chloride in bedrock well BR-3 near the Morton facility, on the one hand, and in seven residential wells in McCullom Lake Village, on the other. Andrews Dep. at 8-9; Andrews Report at 12, Figure A-12. Based on little more than elevated levels of chloride in these two sets of wells, Dr. Andrews declared that the chloride in the Village wells came from the Morton facility. Under Dr. Andrews' model, vinyl chloride first reached the residential wells in the Village in 1972. Andrews Report at Figure 5. Dr. Andrews asserts that the vinyl chloride contamination in the residential wells peaked around 1990 or 1991, and that such contamination continued in the residential wells at a detectable level until about 2002. *Id.*; *see also* Andrews Dep. at 91-94.

In assuming that chloride in the Village wells must have come from the Morton lagoon/landfill, Dr. Andrews and Mr. Hill, too, failed to satisfy the requirements of *Daubert* in three ways: *First*, they failed to perform chemical fingerprinting tests that, if performed, would have shown that the chloride in the McCullom Lake Village wells did not come from the Morton lagoon/landfill. That chemical fingerprinting has now been performed by Rohm and Haas's expert, Robert Mutch, and disproves Dr. Andrews' assumption of an alleged connection between the Morton lagoon/landfill and McCullom Lake Village. *Second*, plaintiffs' experts' flawed methodology is shown by their selective use of data, that is, their decision to ignore elevated chloride concentrations in a McCullom Lake Village well not located on their hypothetical purple plume. *Third*, plaintiffs' experts ignore a well-accepted principle of groundwater migration,

which explains the elevated levels of chloride in the wells as attributable to septic tank waste and road salt.

(1) Fingerprinting analysis shows that the Morton lagoon/landfill is not the source of elevated levels of chloride in the seven residential wells in McCullom Lake Village.

Both Dr. Andrews and Mr. Hill acknowledge that fingerprinting analysis is a generally accepted method of identifying the source of chemicals in groundwater. *See* Andrews Dep. at 10-12; Hill Dep. at 61-65. Each has himself used chemical fingerprinting analysis as a method to determine the source of a contaminant. *Id.* Indeed, Dr. Andrews has performed a fingerprint analysis of chloride to determine its source. Andrews Dep. at 10-12. Yet, neither undertook to compare a fingerprint of the chloride found in the contaminated shallow aquifer (the orange plume) coming from the Morton lagoon/landfill with that found in the McCullom Lake Village residential wells. Andrews Dep. at 10-12; Hill Dep. at 61-67 ("We took no analytical steps" to determine the source of the chloride in the McCullom Lake wells), a critical failure under *Daubert. See Alderman v. Clean Earth*, 2007 WL 1334565 at *6 (Del. Super. Apr. 30, 2007) (finding expert geologist's opinion unreliable because, among other things, he did no fingerprinting: "the expert must do something").

Rohm and Haas did what Dr. Andrews failed to do. That is, rather than just pointing to deficiencies in plaintiffs' evidence, Rohm and Haas performed such a fingerprinting analysis through its expert, Robert Mutch. Mr. Mutch's analysis clearly shows that the source of the chloride in McCullom Lake Village is *not* the Morton lagoon/landfill. Mutch Rebuttal Report (Battle Aff., Vol. I) at 4-10 – 4-22. More specifically, Mr. Mutch first obtained samples from five monitoring wells in and around the contaminated shallow aquifer (the orange plume).

Id. at 4-15. The samples were analyzed for major and minor ions and other parameters, which revealed several distinguishing characteristics, most notably high iodide and bromide levels. *Id.* Mr. Mutch then tested for iodide, bromide, major ions and minor ions in 14 residential wells in and around McCullom Lake Village, selected from among those wells tested by plaintiffs' counsel in January 2007. *Id.* at 4-15 – 4-16. The results showed significant differences in the characteristics of the water in the contaminated shallow aquifer (the orange plume) and the McCullom Lake Village residential wells. *Id.* at 4-18 – 4-20. Most important, the water characteristics in McCullom Lake Village are consistent with septic contamination and *in* consistent with contamination from the Morton lagoon/landfill. *Id.*

In light of *Daubert's* requirements and the results of Mr. Mutch's fingerprinting analysis, the assumption of Dr. Andrews and Mr. Hill that the Morton lagoon/landfill was the source of the elevated levels of chloride in the Village wells cannot stand. Mr. Mutch's fingerprinting analysis affirmatively disproves plaintiffs' experts' assumptions and shows that their hypotheses are utterly unreliable.

(2) The Village well data on which Dr. Andrews and Mr. Hill rely contradict their assumption.

As noted, Dr. Andrews and Mr. Hill acknowledge septic tanks and road salt as potential sources of the elevated chloride concentrations in the shallow residential wells in McCullom Lake Village. However, they say that elevated levels in the deeper wells had to come via Dr. Andrews' hypothetical lower aquifer pathway (his purple plume) from the Morton lagoon/landfill because septic tank waste and road salt could not reach those deeper wells. Instead, they say, there is a vertical upward flow of groundwater beneath McCullom Lake Village that

would prevent septic tank waste and road salt from migrating to the lower aquifer. Their own field data contradict this assumption.

Plaintiffs' field data is easily summarized: of the seven wells with elevated levels of chloride in McCullom Lake Village, four are located on Dr. Andrews' alleged purple plume. Andrews Dep. at 114. Dr. Andrews and Mr. Hill concede they do not know the depth of three of those four so they cannot be counted as deep wells. Andrews Report at Figure A-12; Andrews Dep. at 113-14; Hill Dep. at 79-82. That leaves one well on Dr. Andrews' hypothetical purple plume with an elevated level of chloride that, according to what plaintiffs' counsel told Dr. Andrews and Mr. Hill, is 60 feet deep. Andrews Report at Figure A-12; Andrews Dep. at 113-14. Dr. Andrews and Mr. Hill say the elevated chloride in that one well had to come from the Morton lagoon/landfill because, at 60 feet deep, it is well below the water table and thus allegedly below the reach of more shallow septic tank waste and road salt. Andrews Dep. at 113-14; Hill Dep. at 81-83.

But plaintiffs' *Daubert* problem is the three wells with elevated levels of chloride that are at least 500 feet west of Dr. Andrews' putative purple plume. Andrews Dep. at 114-16; Andrews Report at Figure A-12. One of those three wells is 80 feet below ground surface, and so below the water table. *Id.* at 116. Under Dr. Andrews' and Mr. Hill's hypothesis, the Morton lagoon/landfill *cannot* be the source of contamination in that deep well because it is so far from the purple plume. Neither Dr. Andrews nor Mr. Hill could provide an explanation for this well's elevated level of chloride, other than to say that either the estimation about the depth of the well is wrong — or Dr. Andrews' model is wrong. Andrews Dep. at 116-17; Hill Dep. at 90-92. This kind of result-oriented analysis, clearly intended to advance plaintiffs' theory while disregarding data that contradicts it, is wholly unreliable. *Daubert*, 509 U.S. at 590-92 (expert's theory should

be rejected when it is the result of a subjective, conclusory approach that cannot reasonably be assessed for liability).

(3) Dr. Andrews and Mr. Hill ignore a well-founded principle that explains the elevated level of chloride in the deep wells of McCullom Lake Village, both on and off Dr. Andrews' purported plume

It is an accepted principle of hydrogeology that when people use well water on a daily basis, they create a downward hydraulic draw of groundwater. Mutch Rebuttal Report at 2-19. In other words, as a deeper residential well draws water up to a house, it simultaneously pulls groundwater that was closer to the surface down. *Id.* In McCullom Lake Village, there are more than 400 houses, each with its own well, collectively drawing thousands of gallons of groundwater for residential use every day. *Id.* This unceasing downward hydraulic draw provides an explanation for how shallow water contaminants, including chloride, could reach the two deeper wells, one on Dr. Andrews' theoretical plume and the other 500 feet to the west.

Dr. Andrews acknowledges the validity of this hydrogeologic principle but simply refuses to accept it as the explanation for how chloride from septic tanks and road salt could reach the deeper wells. Andrews Dep. at 117-119. Doing so would, of course, destroy his assumption that the Morton lagoon/landfill is the source of the elevated levels of chloride in the deep residential wells.

* * *

In sum, the assumptions of Dr. Andrews and Mr. Hill that the Morton lagoon/landfill was the source of the elevated levels of chloride in the deeper wells of McCullom Lake Village cannot withstand a *Daubert* analysis.

b. SECOND UNFOUNDED ASSUMPTION: The Facts Do Not Support Dr. Andrews' Assumption as to the Volume of Past Disposal into the Lagoon/Landfill

To calculate the volume of vinyl chloride that allegedly reached McCullom Lake Village, Dr. Andrews assumes that Morton disposed of 72,000 gallons a day — that is, about 26,200,000 gallons per year — of wastewater into the lagoon/landfill from 1961 through 1977. Andrews Report at 11; Andrews Dep. at 107-08. As explained below, the available evidence contradicts that assumption and would support a flow of no more than 5,000 to 30,000 gallons per day, or 1,200,000 to 7,200,000 gallons per year. Reducing the flow to the level consistent with the facts would materially impact Dr. Andrews' model and significantly decrease the estimated volume of vinyl chloride that would have reached McCullom Lake Village under Dr. Andrews' hypothesis. Andrews Dep. at 105. As Dr. Andrews has admitted, his calculated waste stream affected the amount of water (and, therefore, contaminants) in his hypothetical purple plume. *Id.* at 109-10.

(1) The Documents Contradict Dr. Andrews' Assumption.

Dr. Andrews bases his 72,000-gallons-a-day, 26,200,000 per year, figure upon his review of manufacturing documents concerning Morton's operations in the 1960's and 1970's.

Andrews Report at 11; Andrews Dep. at 100-05 & Ex. 8.

However, there is nothing in those documents that would support (a) Dr. Andrews' 72,000-gallons-per-day figure, ³ or (b) Dr. Andrews' assumption that Morton was dispos-

^{3.} Indeed, Dr. Andrews' figure is at odds with that of Mr. Hill, who, after reviewing many of the same documents, decided that Morton was disposing of approximately 50,000 gal....Continued

ing of wastewater into its lagoon/landfill 365 days a year. On the contrary, the documents show that daily disposal volume was much lower and that such disposal occurred approximately 240 days a year, that is, 5 days a week. *See* Andrews Report at Table 1, n.3; Andrews Dep. at Ex. 8.

(2) The Deposition Testimony Contradicts Dr. Andrews' Assumption.

Daniel Schmitt, the former general manager of Morton's facility, testified that the actual daily disposal volume ranged between 5,000 and 30,000 gallons per day. Mutch 2008 Report (Def. Opp. to Class Certif., Ex. A) at 4-5 – 4-6 (citing witness testimony). Dr. Andrews cites no evidence that the facility operated on weekends or holidays.

If Mr. Schmitt's high estimate of 30,000 gallons per day for 5 days per week is used, then the annual volume of wastewater into the lagoon/landfill would be 7,200,000 gallons. So Dr. Andrews' figure of 26,200,000 is nearly four times higher than the highest possible volume based on the available evidence.

When asked why he did not consider Mr. Schmitt's deposition testimony, Dr. Andrews replied that plaintiffs' counsel had not provided him with the transcript. Andrews Dep. at 109-10. But even after learning of Mr. Schmitt's estimate, Andrews refused to budge from his 26,200,000 figure — presumably because to do otherwise would destroy his opinion. *Id.* at 104-05. Dr. Andrews has no facts on which to base his opinion. For that reason, it is unreliable.

lons per day for 5 days a week for a total of 12,000,000 gallons per year — less than half the volume figure used by Dr. Andrews. Hill 2006 Report at 5.

Continued from previous page

c. THIRD UNFOUNDED ASSUMPTION: Contrary to Dr. Andrews' Hypothesis, There Is No 1,500-Foot-Wide Corridor of Sand and Gravel.

For purposes of his groundwater model, Dr. Andrews assumes that the lower aquifer between the Morton facility and McCullom Lake Village is made up of a highly permeable sand and gravel corridor about 1,500 feet wide with low permeable till on either side. Andrews Report at 6-7, 9, 13. In other words, he says that the geology created a channel of permable material surrounded by less permeable walls, creating an underground path. This hypothetical sand and gravel corridor in the lower aquifer is crucial to Dr. Andrews' model because, under Dr. Andrews' hypothesis, that is what allowed contaminated groundwater to flow from the Morton facility to the residential wells in the eastern portion of the Village.

Dr. Andrews' assumption is based solely on the fact that boring logs from BR-3 and MD-WW-1 show sand and gravel just above bedrock in the lower aquifer. Andrews Report at 7. However, BR-3 and MD-WW-1 are close together on the former Morton facility and so, without more, are hardly sufficient to support Dr. Andrews' assumption such that a corridor runs the entire 1½ mile stretch from the former Morton facility to McCullom Lake Village. Mutch Rebuttal Report at 2-3, 2-7.

Dr. Andrews also points to an Illinois State Geological Survey prepared by B.B. Curry (hereinafter "the Curry Report") and other geological studies by J.D. Stravers to support his assumption. But those reports do not say there is any such corridor.

Both Dr. Andrews and Mr. Hill concede, as they must, that the most accurate method of determining the nature of the material in the lower aquifer would be to install wells in the 1½ mile area between the former Morton facility and McCullom Lake Village. Such wells

would show whether the geologic conditions there were as supposed by Dr. Andrews. But no such wells were installed by Dr. Andrews or Mr. Hill. Their failure to do any such work or to take steps to gather hard data to back up their suppositions renders them inherently unreliable. *See Alderman*, 2007 WL 1334565, at *5-*6 (finding expert geologist's opinion unreliable under *Daubert* for failure to collect facts to test his theory).

Here, again, it was Rohm and Haas that undertook to find out the real facts. Within the past few months, Rohm and Haas installed a confirmatory monitoring well system consisting of three wells in the lower aquifer in the 1½ mile stretch between the facility and the Village (BR-4, BR-5 and BR-6). That is, Rohm and Haas did exactly what plaintiffs' experts should have done. The boring logs from all three of these wells show a geological make-up completely different from Dr. Andrews' hypothesized sand and gravel pathway. More specifically, these boring logs show much-less-permeable till in place of the sand and gravel Dr. Andrews assumes in his model. Mutch Rebuttal Report at 4-5 – 4-6, Figure 4-2.

In short, once again, the field data directly and plainly contradict Dr. Andrews' assumption. His opinion does not satisfy the threshold requirement of Federal Rule of Evidence 702 that expert testimony must be based on sufficient facts or data.

d. FOURTH UNFOUNDED ASSUMPTION: Contrary to Dr. Andrews' Hypothesis, the Lower Aquifer Does Not Flow in a Southerly Direction.

Piling assumption upon assumption, Dr. Andrews next supposes that the ground-water in the lower aquifer flows in a southerly direction — rather than in a southeasterly direction like the thoroughly delineated upper aquifer. Andrews Report at 12. This purported southerly flow is critical to plaintiffs' case. If, as in the upper aquifer, the groundwater flow in the

lower aquifer is southeasterly, then contamination from the Morton facility could not reach the residential wells of McCullom Lake Village.

Dr. Andrews admits he relied on very limited information concerning the direction of the groundwater flow in the lower aquifer. Again he conducted no tests. Andrews Report at 8. He assumes the flow is in a southerly direction towards McCullom Lake Village on the basis of only (a) selective portions of a 1998 hydrogeology report, and (b) water levels in the bedrock wells near the Morton facility. Andrews Report at 8. Neither supports Dr. Andrews' assumption.

(1) Dr. Andrews selectively uses data from the 1998 Meyer Report.

While a 1998 report on hydrogeological conditions in McHenry County (which includes McCullom Lake Village and the Morton facility) prepared by Scott Meyer (hereinafter "the Meyer Report") shows a southerly groundwater flow in the immediate vicinity of the Morton facility, that same report notes that the groundwater in the lower aquifer flows in a southeasterly (not southerly) direction as it moves beyond the Morton facility. Mutch Rebuttal Report at 2-21 (discussing the Meyer Report). Indeed, when presented at his deposition with a contour map based upon the findings in the Meyer Report and asked to plot the groundwater flow, Dr. Andrews himself plotted a southeasterly flow that avoided McCullom Lake Village. Andrews Dep. at Ex. 16. In other words, in creating his model, Dr. Andrews ignored those portions of the Meyer Report that contradicted the assumption he was so eager to make. As noted above, when an expert "cherry picks" facts, his opinion becomes unreliable and fails to satisfy a *Daubert* analysis. *Barber*, 17 Fed. Appx. at 437.

(2) New data confirms that the groundwater flows to the southeast.

Dr. Andrews also bases his opinion regarding the direction of the groundwater flow on sampling results from a handful of on-site bedrock monitoring wells installed by Rohm and Haas in November 2006 and from wells WW-3 and -4, which are located in the lower aquifer near the Morton facility. Andrews Report at 6-8, 12. That skimpy data was insufficient to support Dr. Andrews' theory. Perhaps more important, subsequent fact investigation has disproved Dr. Andrews' guess.

Although not its burden, Rohm and Haas collected field data from wells installed in the lower aquifer in the 1½ mile stretch between the Morton facility and McCullom Lake Village: they confirm the Meyer Report's conclusion that the groundwater there flows to the southeast, not to the south. Mutch Rebuttal Report at 4-9 – 4-10, Figures 4-3, 4-4. Once again, Dr. Andrews' assumption evaporates in the light of the facts.

e. FIFTH UNFOUNDED ASSUMPTION: There Is No Scientific Support for Dr. Andrews' Use of a 10% Porosity Rate in the Lower Aquifer.

How quickly groundwater and its constituents will travel is a function of the porosity rate of the material through which they move. Porosity evaluates the ratio of the volume of pores in a material to the total volume. Thus, the higher the porosity rate, the slower they will travel.

In his expert report, Dr. Andrews states that the correct porosity rate for sand and gravel is 20%. Andrews Report at 15. But, curiously, at his deposition, he insisted he had used a 15% porosity rate in his model. Dr. Andrews vigorously defended his use of 15%, explaining, "the basis for [15%] is my professional experience and judgment that that is the appropriate

value," Andrews Dep. at 49-50, adding that he "frequently" used 15% in models for sand and gravel. *Id.* at 51. But, as Dr. Andrews ultimately conceded, the truth is that, for all his insistence that 15% is the correct porosity rate, the backup documentation from his model shows he actually used 10%. *Id.* at 52-53. With that 10% rate, Dr. Andrews' model projected that it would take approximately 30 years (until the early 1990s) for the peak of the supposed purple plume to reach McCullom Lake Village. Andrews Report at Figure 5. There is no scientific justification for a 10% porosity rate.

Numerous peer-reviewed studies have concluded that the porosity rate for sand and gravel is usually between 20% and 40%. Mutch Rebuttal Report at 2-16 – 2-17 (collecting literature). That is, those studies show that Andrews was closer to right when he said in his report that 20% was the correct rate. At his deposition, Dr. Andrews tried to explain them all away by saying that there is a difference (that need not be explained here) between effective and total porosity rates in sand and gravel. Andrews Dep. at 46-48, 50, 88-90. When shown texts explaining that there is no difference between effective and total porosity for calculating the porosity rate in sand and gravel, Dr. Andrews said he disagreed with all of these authorities and insisted that his use of a 10% rate was appropriate. *Id.* at 50, 53, 55.

When pressed to identify authority for his selected porosity rate of 10%, Dr. Andrews cited a lone 1998 article by Daniel B. Stephens, *A Comparison of Estimated and Calculated Porosity*, HYDROGEOLOGY JOURNAL (1998) at 156 (hereinafter "the Stephens Article") (Battle Aff., Vol. IV, tab 11). But the Stephens Article provides no support for Dr. Andrews' use of a 10% porosity rate. On the contrary, the Stephens Article noted that a "field tracer test" in a sand and gravel aquifer determined that the porosity rate was *17%*. Stephens Article at 156; Mutch Rebuttal Report at 2-16 –2-17. In other words, the lowest porosity rate the Stephens Arti-

cle would support here — 17% — is far above the 10% Dr. Andrews used. Had Dr. Andrews used a 17% porosity rate in his model, the peak of the hypothetical purple plume would not pass through McCullom Lake Village until about 2012, which is clearly at odds with Dr. Andrews' speculative theory that it came and went by 2002. Finally, although the Stephens Article concluded that the porosity rate "is best obtained by laboratory or field tracer tests," Stephens Article at 156, Dr. Andrews performed neither: instead, he used a 10% porosity rate for which there is no scientific support, presumably because that is the only way he can get to his preordained conclusion.⁴

* * * *

In short, Dr. Andrews' model is based upon a series of plainly inaccurate and unreliable assumptions. Dr. Andrews failed to collect necessary field data, cherry-picked facts, and ignored peer-reviewed literature. As the Third Circuit has observed, an expert's "opinion based on false assumptions is unhelpful in aiding the jury in its search for the truth, and is likely to mislead and confuse." *Advent*, 925 F.2d at 682, *quoting Wilkinson*, 712 F. Supp. at 479. Because Dr. Andrews' model is based upon false and unreliable assumptions, it must be excluded under *Daubert*. Since Mr. Hill's opinion is admittedly based primarily on Dr. Andrews' unreliable model, it too should be excluded.

^{4.} Moreover, the Stephens Article does not address the comparison between total porosity and effective porosity; nowhere in that article are those concepts compared. Instead, the article focuses on the difference between calculated values of effective porosity through a field tracer test in a sand-and-gravel aquifer and the textual estimates of effective porosity. Mutch Rebuttal Report at 2-16 – 2-17.

B. DRS. PAOLO ZANNETTI AND JUNE ANN OBERDORFER

Plaintiffs theorize that, apart from the vinyl chloride that they say traveled to McCullom Lake Village via their hypothetical purple plume, class members were also exposed to some amount of airborne vinyl chloride emanating from the shallow groundwater plume (the orange plume) adjacent to the defendants' plant over a mile away. Plaintiffs claim that vinyl chloride was carried to McCullom Lake Village with the wind. In support of this theory, plaintiffs rely on the expert opinion of Dr. Paolo Zannetti, who in turn bases his opinion on work performed by Dr. June Ann Oberdorfer. But because Dr. Oberdorfer stacked one unsupported assumption atop another to reach an extremely strained — indeed, impossible — result, the entire analysis by the plaintiffs' air modeling team is unreliable under *Daubert* and of no use in evaluating the actual air exposures of people in McCullom Lake Village.

Ultimately, Dr. Oberdorfer produced two sets of emission rates for four different time periods ranging from 1940 to the present. The first set, which she calls her "low scenario," is, she now admits, actually the average. The second, which she calls her "high scenario," is, she now admits, actually an artificially high peak — the highest rate that could ever have existed if

^{5.} A third member of Dr. Zannetti's team, Dr. Michael Jennings, also analyzed emissions from an "air stripping" tower used by defendants to remediate the known shallow plume adjacent to the plant between 1990 and 2004 and originally claimed that the air stripper contributed to the alleged air contamination in the Village. But plaintiffs' experts have since acknowledged that Dr. Jennings' calculations of 1,1-DCE, from which the vinyl chloride allegedly degraded, were erroneous. Zannetti Dep. at 211-13. Moreover, plaintiffs' experts agree with defendants' expert on both the concentrations of vinyl chloride emitted from the air stripper and that the air stripper's contribution to airborne contamination "is not dominant." *Id.* at 212-13.

every assumption were made in favor of that "high," regardless of how extreme or unfounded the assumptions.

Taking *only* Dr. Oberdorfer's "high" or "peak" calculations, Dr. Zannetti then applied standard air modeling simulations to conclude that, between 1940 and 1967, residents at the northern border of McCullom Lake Village were exposed to an average concentration of 0.239 micrograms per cubic meter (μg/m³) of vinyl chloride — just above EPA's present lifetime risk level of 0.23 μg/m³. But, again, because the key to his model (Dr. Oberdorfer's calculations) has no basis in reality, neither do Dr. Zannetti's conclusions.

Importantly, because Dr. Zannetti posited no exposure above the EPA risk level for any year actually in the proposed class period, his opinion is singularly unhelpful to the trier of fact in determining whether exposures in the putative class area were sufficiently high and sufficiently uniform to warrant class certification.

1. BACKGROUND

a. Dr. Oberdorfer's Emission Rate Calculations.

Dr. Oberdorfer professes to have calculated the rate at which vinyl chloride volatized (*i.e.*, was emitted into the air) from the shallow groundwater plume. She did so using the Farmer Model, a standard EPA-approved model. But her calculations depend, among other variables, on (1) the size of the groundwater plume, (2) the time period over which volatization occurred, and (3) the concentrations of vinyl chloride found in the plume. *See generally* Enviro-Comp Report (Pl. Repl. Br., Ex. H), Appx. D. An error in any one of these parameters can have a dramatic impact on the accuracy of the calculations. As shown below, at each step of her analysis, Dr. Oberdorfer ignored the actual available data. Instead, she cherry-picked facts, made

assumptions with no basis in fact or science, and failed to use simple, scientific methods to test the accuracy of her calculations. In other words, the "inputs" to her calculations are just plain wrong — and so, naturally, the "outputs" are wrong too — and she did nothing to check her work.

Dr. Oberdorfer's unsubstantiated assumptions for these parameters can be summarized as follows:

- Dr. Oberdorfer assumed that the size of the orange groundwater plume in 2006, which is estimated at approximately 60 acres, has been constant from the first day that Morton began operations in 1940, even though she acknowledges that it would take at least ten years for the plume to reach that size, EnviroComp Report, Appx. D, at 5, 9; Oberdorfer Dep. at 35-37, 67; and even though remediation maps show that the plume was much smaller even in the 1980s. Drivas Report (Battle Aff., Vol. II) at 7-9.
- Dr. Oberdorfer assumed that the Morton/Rohm and Haas facility was releasing 1,1-DCE (and therefore its breakdown product, vinyl chloride) into the groundwater from the very day that the facility began operations in 1940, even though the only manufacturing process at the plant that uses 1,1-DCE did not begin until 1959. EnviroComp Report Appx. D at 5, 9; Andrews Dep. at 21.
- Although Dr. Oberdorfer used monitoring well data gathered over the course of defendants' 18 years of remediation work at the plant site, she did not consider *all* of the monitoring wells in calculating the average concentration of vinyl chloride. Instead, Dr. Oberdorfer selected only those monitoring wells with, in her opinion, a "substantial" amount of contamination. EnviroComp Report Appx. D at 3.
- Dr. Oberdorfer failed to take into account the impact of snow in northern Illinois (where McCullom Lake Village is located) on capping air emissions from the plume during the winter months. Oberdorfer Dep. at 167-69.
- Dr. Oberdorfer assumed that the concentrations of the contaminants found in monitoring-well samples as far as 30 feet below the ground surface were the same as that at the top of the water table, which is directly below the ground surface, ignoring the fact that water near the surface is typically much cleaner due to displacement by clean rain water. Oberdorfer Dep. at 166-168.

As if these strained assumptions were not enough, Dr. Oberdorfer went a step further. She created two emission rates, a "high" and a "low" rate. For her high estimate of the emission rate, she took the highest reading in a particular monitoring well and assumed that reading for entire blocks of time, even though many wells showed a much lower concentration at other times during the same period. *See*, *e.g.*, Oberdorfer Dep. at 42-58. For what Dr. Oberdorfer called her "low" rate, she did not take the lowest reading from each of the wells she used, but instead took the *average* of all of the readings from the wells during a particular time period. *Id.* at 40-44.

b. Dr. Zannetti's Air Modeling.

Dr. Zannetti had a problem using Dr. Oberdorfer's calculation of the *average* emission rate from the orange plume (again, what Dr. Oberdorfer called her "low"): when those average rates were plugged into his air modeling program, it appeared that the residents at the very northernmost point of McCullom Lake Village, closest to the plume, had faced an exposure rate of only $0.0159 \, \mu g/m^3$ — a rate 15 times below EPA's established risk assessment standard of $0.23 \, \mu g/m^3$, and below the background rate for vinyl chloride in the area. Drivas Report at 4. Obviously, for residents further away from the plume, and people who lived there during time periods of lower emissions, the exposure rate would be even lower. *Id.*

So Dr. Zannetti set aside the average and instead looked to Dr. Oberdorfer's "high" estimate — which, again, was calculated by using only the cherry-picked, highest-ever numbers available and ignoring contradictory data. Using *those* numbers, Dr. Zannetti's model resulted in a vinyl chloride exposure rate of 0.239 μ g/m³ for the time period 1940-1967 — ever so slightly higher (just 9/1000th higher) than the EPA threshold. (Notably, this is the *only* time

period for which Dr. Zannetti's modeling provided an exposure rate above the present EPA threshold: even using Dr. Oberdorfer's high emission rate, the model did not predict an exposure over that threshold for any time period actually in the proposed class period. *See* EnviroComp Report at 34. Even under Dr. Zannetti's model, the central and southern portions of the Village would not be exposed above the present EPA threshold during the 1940-1967 time period. *See id.* at 23.)

2. ARGUMENT

The Zannetti team's approach fails the Rule 702 test. Although they used standard modeling methodologies, neither Dr. Zannetti nor Dr. Oberdorfer used the correct facts or data in applying those methodologies. As such, their analyses are singularly unhelpful — indeed, misleading — to the trier of fact, and do not fit the actual facts of the case.

a. Dr. Oberdorfer's Assumptions Are Unreliable.

As noted above, Dr. Oberdorfer made a number of assumptions about the facts that are just plain wrong. In particular, those assumptions affect three critical parameters of her model — the area of the plume, the time period of the emissions, and the concentrations of vinyl chloride in the groundwater. Any one of these erroneous assumptions — all of which are skewed in plaintiffs' favor — would affect the accuracy of her results dramatically, but the cumulative result is that her entire calculation is completely unreliable and scientifically unsound. And, to top it all off, Dr. Oberdorfer took no steps to test the accuracy of her results, even though well-recognized tests are readily available.

(1) Dr. Oberdorfer's Assumptions as to the Size of the Plume Are Wrong.

Under the model Dr. Zannetti used, the larger the area of the plume, the greater the volume of vinyl chloride that is volatizing. Oberdorfer Dep. at 35-37; Drivas Report at 7. It is undisputed that defendants have been investigating and remediating that plume since the mid-1980s, during which time the plume has gradually migrated in the shallow groundwater in a southeasterly direction away from the plant — and away from McCullom Lake Village.

Instead of looking at the last 20-plus years of data on the size and location of the plume, however, Dr. Oberdorfer simply took the size of the groundwater plume in 2006, after several decades of its gradual expansion and migration, and assumed that the entire 60-acre plume existed as-is from the first day Morton began operations in 1940. *See* EnviroComp Report, Appx. D at 5, 9; Oberdorfer Dep. at 67.

This makes no sense. Plaintiffs' own hydrogeologist has acknowledged that the manufacturing process from which the vinyl chloride contamination ultimately resulted (as a breakdown product of another chemical, 1,1-DCE) did not begin until 1959. Andrews Dep. at 21. The landfill which is generally believed to be the primary source of groundwater contamination was not put into use until 1961. Andrews Dep. at 108. Dr. Oberdorfer herself has admitted that her calculations are wrong because it would take at least ten years for the plume to reach its current size. Oberdorfer Dep. at 36. And defendants' remediation consultants have mapped the growth of the plume since the 1980s, demonstrating with actual data that it was considerably smaller in earlier years and has only slowly grown to its current size. Drivas Report at 7-9.

Not only did Dr. Oberdorfer's approach ignore known facts, but it is contrary to accepted hydrogeological methods. Dr. Zannetti admitted that even where there is insufficient

data to calculate the growth of a groundwater plume, there are accepted methods (known as "inverse modeling" or "hindcast") that modelers can and should use to at least estimate the changing size of a plume over a specific time period. Zannetti Dep. at 128-34. Dr. Oberdorfer employed none of these methods. *Id.*

Again, these erroneous assumptions skewed the results of her calculations in plaintiffs' favor: Dr. Oberdorfer assumed the largest possible area of emissions over the longest possible period of time. Had she considered the actual facts, her predicted air emissions would have decreased by approximately a factor of 10. Drivas Report at 8. In short, Dr. Oberdorfer's assumption that the plume has remained constant and at its largest size from 1940 to 2006 is undeniably wrong, inconsistent with the actual data, inconsistent with accepted methodology in the hydrogeology field, and inconsistent with common sense.

(2) Dr. Oberdorfer Miscalculated the Time Periods of Emissions.

Ignoring the undisputed facts of record, Dr. Oberdorfer assumed that vinyl chloride emissions began in 1940 — again, nearly 20 years before the source of vinyl chloride was even present at the plant. Andrews Dep. at 21; Oberdorfer Dep. at 32-34. Thus, for the years 1940 to 1959, her data is totally invented. Even for the time period between the plant's initial use of 1,1-DCE and its installation of monitoring wells, Dr. Oberdorfer invented data to fill the gap. Instead of limiting herself to the time period for which actual monitoring well data exists, Dr. Oberdorfer extrapolated backwards from later well tests. In other words, where she had no data from which to work (as, for example, for the time period 1940-1967), she just made it up and filled in the blanks. As a result, Dr. Oberdorfer ended up concluding that the vinyl chloride was volatizing into the air between 1940 and 1959 at a higher rate than during any time period

when 1,1-DCE *was* used at the plant. *See* EnviroComp Report, Appx. D at 5. There is no scientific basis for these assumptions, particularly where, as discussed above, the data already show that the plume did not remain constant over time. Again, Dr. Oberdorfer's "facts" skewed her calculations to favor plaintiffs.

(3) Dr. Oberdorfer Unscientifically Cherry Picked Vinyl Chloride Concentrations.

A critical parameter for Dr. Oberdorfer's model is the concentration of vinyl chloride in the groundwater, which, naturally, affects how much vinyl chloride could escape into the air. Here, Dr. Oberdorfer made two critical errors: She ignored vast amounts of data, and she ignored the effects of precipitation.

Dr. Oberdorfer relied on the monitoring well data provided by defendants to figure out the concentration of vinyl chloride in the groundwater. But she did not consider all of the data available. Instead, she selected 8 wells that, in her view, showed a "significant" amount of contamination, and disregarded wells with lower concentrations. EnviroComp Report, Appx. D at 3. Considering just these 8 wells, she calculated her so-called "low" (but really average) emission rates.

Not content to stop there in her quest to inflate the emission rate, Dr. Oberdorfer next decided to calculate a "high" emission rate. This time, instead of considering all of the sampling done in the 8 wells she had already cherry picked, she now decided to use only the highest concentrations from all of the sampling ever done in those wells. Oberdorfer Dep. at 44-49. She then assumed that those highest concentrations existed during the entire early time periods at issue, ignoring numerous other samplings showing significantly lower concentrations in those same wells. *Id.* And she nearly doubled the air-filled porosity rate in the soil so that the volati-

zation of vinyl chloride from the water table would be even greater. EnviroComp Report, Appx. D at 1-2. The law under *Daubert* and Rule 702 clearly prohibits such selective consideration of data. *Barber*, 17 Fed. Appx. at 437 (where expert "cherry-picked the facts he considered to render an expert opinion, the district court correctly barred his testimony because such a selective use of facts fails to satisfy the scientific method and *Daubert*"); *In re Bextra & Celebrex Mktg*. *Sales Practices and Prod. Liab. Litig.*, 2007 U.S. Dist. LEXIS 86382 (N.D. Cal. Nov. 19, 2007), at *60-*69 (same).

Dr. Oberdorfer's selective use of data resulted in an analysis full of absurdities. For instance, take monitoring well MW-9. In the late 1980's, this well was sampled twice. EnviroComp Report, Appx. D at Att. 1. The average vinyl chloride concentration was 28 micrograms per liter (μg/l). *Id.* In the early 1990's, it was sampled another four times with an average vinyl chloride concentration of 14 μg/l. *Id.* And, since the late 1990s, another ten samples have shown the average concentration to be 30 μg/l. *Id.* Yet, in determining the vinyl chloride concentrations for the nearly 50-year period from 1940 to 1989, Oberdorfer ignored all of this data and instead picks a single sampling result from May 2000, when the vinyl chloride concentration spiked up to 110 μg/l. EnviroComp Report, Appx. D at 4, Table 2. She then applied that concentration to the entire time period from 1940 to 1989. *Id.* In other words, Dr. Oberdorfer extrapolated from a single, anomalous well test and ignored fifteen other samples from the same well.

MW-8 provides another illustration. The only data available for this well before 1992 are two samples from 1985 and 1989, which showed concentrations of vinyl chloride of 13 μg/l and 22.8 μg/l, respectively. EnviroComp Report, Appx. D at Att. 1. Yet, Dr. Oberdorfer ignored this field data from that time period. Instead, she used a sampling result from MW-8 in

1992 of 180 μ g/l, and then assumed that from 1940 to 1989 — a period of 49 years — the concentration in that well was a constant 180 μ g/l. *Id.*, Appx. D at 4, Table 2.

Dr. Oberdorfer's high emission rate calculation is plain junk science. It is nothing more than an amateurish attempt to artificially inflate the emission rate even further. It is, therefore, simply misleading to the fact finder and should be excluded.

(4) Dr. Oberdorfer Ignored Precipitation.

Dr. Oberdorfer further strained her model by failing to account in any way for precipitation. First, she ignored the snow. Unlike San Francisco, where Dr. Oberdorfer resides, the region in which McCullom Lake Village is located receives substantial snowfall every winter. Indeed, as Dr. Zannetti acknowledged in his expert report, the National Climate Data Center notes that, while snowfall from month to month and year to year is greatly variable, "[t]here is a 50 percent likelihood that the first and last 1-inch snowfall of a season will occur by December 5 and March 20, respectively." EnviroComp Report at 12. In other words, one can expect snow to be covering the ground above the plume a significant part of the time during about a quarter of every year. All agree that snow acts as a cap atop the soil, preventing any vinyl chloride from escaping into the air. Oberdorfer Dep. at 71-73, 168-69. Dr. Oberdorfer simply ignored this fact and assumed that no snow is going to fall in McHenry County, ever. *Id*.

Dr. Oberdorfer also ignored the effect of precipitation when she decided to use well data from as far as 30 feet below the ground surface, and assumed that the concentrations of vinyl chloride at those depths were the same as at the top of the saturated zone near the water table. Oberdorfer Dep. at 69-70. Dr. Oberdorfer admitted that the only area where contaminants can volatize into the soil and ultimately into the air is at the top of the saturated zone near the wa-

ter table. EnviroComp Report, Appx. D at 1-2. It is generally accepted in the hydrogeology field that even where there is a plume, groundwater closer to the surface is substantially cleaner than at deeper levels, because clean rain water displaces the contaminated water and dilutes the concentrations of contaminants. Drivas Report at 11 (noting that Chicago area gets 34 inches of rain per year on average).

Dr. Oberdorfer ignored this generally accepted principle. Oberdorfer Dep. at 71-72. What is more, actual field data generated since she submitted her report demonstrates conclusively that, in accord with the generally accepted expectation, such a clean water "wedge" is in fact in place at the top of the plume. At the direction of Robert Mutch, five temporary hydropunch wells were installed along the full length of the plume and near monitoring wells where concentrations of volatile organic compounds (including vinyl chloride) had been documented during previous sampling events, with one location selected because it represented an area of groundwater discharge. Mutch Rebuttal Report at 4-23. As expected, the concentration of vinyl chloride in four of the five wells at the top of the water table was insignificant, showing that volatization is minimal over most of the plume. *Id.* at 4-27 – 4-28; Drivas Report at 11-12.

Dr. Oberdorfer's assumptions on this point — again designed to skew her results in plaintiffs' favor — were baseless to begin with, and have now been proven factually incorrect.

(5) Dr. Oberdorfer Unscientifically Failed to Check Her Work.

A critical question courts consider in evaluating the admissibility of an expert opinion is whether there are ways to test the accuracy of that opinion. *See Daubert*, 509 U.S. at 590 n.9. Although Dr. Oberdorfer could have tested the accuracy of her emission rate calcula-

tions, neither she nor Dr. Zannetti bothered to do so. Oberdorfer Dep. at 75-76; Zannetti Dep. at 74-75. When her rate is tested, it fails miserably.

One way to test the accuracy of Dr. Oberdorfer's work is to determine if there is enough vinyl chloride in the groundwater to support her emission rate. Drivas Report at 13. In other words, if the emission rate adopted by Dr. Oberdorfer would lead to the volatization of more vinyl chloride into the air than existed in the groundwater plume, then this emission rate must be too high. *Id.* This sort of check on calculations is a common and simple method to make sure that the parameters being used in an emission rate model are physically possible and not inconsistent with reality. In fact, at his deposition, Dr. Zannetti admitted that he has done this type of cross-checking of his calculations many times. Zannetti Dep. at 74. Yet, in this case, neither he nor Dr. Oberdorfer undertook such an analysis with respect to the emission rates developed by Dr. Oberdorfer. *Id.*

If they had, they would have learned that the emission rates adopted by Dr. Oberdorfer are impossibly high. Indeed, Dr. Oberdorfer's emission rate could only be right if there were 35 times the amount of vinyl chloride in the plume than objective well test data show is actually there. Drivas Report at 13-17. In short, Dr. Oberdorfer's calculations don't make sense, and — as shown in the Drivas Report, page 21 — are totally out of line with reality.

b. Dr. Zannetti's Analysis Failed.

Even assuming for purposes of argument that Dr. Oberdorfer's emission rates were reliable (which is belied by the discussion above), Dr. Zannetti's opinion is still inadmissible because it has *nothing to do with actual exposure in McCullom Lake Village*. Even where the data and method are reliable, courts must examine how they have been applied to determine

whether the expert's conclusions "reliably follow from the facts known to the expert and the methodology used." *Schieber*, 2000 U.S. Dist. LEXIS 7952, *8. The testimony offered and the facts of the case must "fit." *Id*.

Here, Dr. Zannetti is supposed to be providing an opinion to a reasonable degree of professional certainty as to the actual exposure rate for vinyl chloride in McCullom Lake Village. But that is not what his model simulations represent. Instead, as Dr. Zannetti admitted at his deposition, the cherry-picked "high scenario" supplied by Dr. Oberdorfer was not the "best estimate" of the actual emission rate — but rather a "higher estimate." Zannetti Dep. at 55-56. When Dr. Zannetti performed his air model simulations purporting to show "average" exposures in the Village, he used only the high scenario. *Id.* at 22-34. In other words, by Dr. Zannetti's own admission his air model simulations cannot be to a reasonable degree of professional certainty because they are based upon an emission rate that he admits is *not* the "best estimate." *Id.* at 55-56.

These air model simulations based upon totally fictional high emission rates have distorted other aspects of plaintiffs' case. Dr. Zannetti has provided his air modeling results to Dr. Gary Ginsberg, plaintiffs' toxicologist, who has only considered Dr. Zannetti's "high scenario" modeling results in conducting his risk assessment for the putative class members' alleged exposure to vinyl chloride. Ginsberg Report at 34-35. Thus, Dr. Oberdorfer's flawed and inadmissible calculations have infected plaintiffs' entire case.

C. DR. GARY GINSBERG

Dr. Gary Ginsberg is a toxicologist with the Connecticut Department of Public Health. His report has two components: (1) an "exposure estimate" that purports to quantify a high-end estimate of class members' vinyl chloride-exposure; and (2) a "risk assessment" based on this high-end estimate.

Neither satisfies *Daubert*:

- 1. The exposure estimate is based on improper data and a flawed methodology. Among other things, Dr. Ginsberg deliberately inflated his estimate of the alleged levels of vinyl chloride in the outdoor air by adopting only the so-called "high" scenario created by plaintiffs' air modelers, and he used artificial assumptions in calculating the levels of vinyl chloride that supposedly would have volatized into the indoor air of houses directly above Dr. Andrews' hypothetical purple plume. Dr. Ginsberg says he used these inflated estimates because his aim was not to determine class members' *actual* risk; instead, he wanted to see what the risk "could have been as high as."
- 2. The risk assessment, too, is based on a flawed methodology: in the absence of any evidence that vinyl chloride exposure increases the risk of developing brain cancer, Dr. Ginsberg "adjusts" regulatory agency estimates of the risk for *liver* angiosarcoma from vinyl chloride exposure a method endorsed by no one and for which Dr. Ginsberg can cite no authority. In addition, the risk assessment is decidedly unhelpful to the Court or trier of fact, since it is just a *range* of risks that Dr. Ginsberg says "could be" applicable to a small subset of class members.

1. BACKGROUND

a. The Exposure Estimate

Dr. Ginsberg postulates two sources of vinyl chloride exposure class members purportedly experienced: (1) outdoor volatization from water in the shallow (orange) plume that is southeast of the Rohm and Haas facility, and (2) indoor volatization from well water used in houses directly above Dr. Andrews' hypothetical purple plume.

Outdoor exposure. Dr. Ginsberg's estimate of the alleged outdoor air concentrations of vinyl chloride in the Village is 0.127 μg/m³ for the 25-year period from 1978 to 2002. Ginsberg Report at 34. He derived this estimate solely from the falsely inflated "high" air emission scenario calculated by the Zannetti team. He never bothered to calculate an estimate using Dr. Zannetti's "low" scenario, which, though called "low," is actually based on an average of water concentrations shown by well readings. Ginsberg Dep. II at 185-86.

Dr. Ginsberg says he used only the Zannetti team's "high" scenario because —

where you're trying to establish whether or not a community needs to be monitored . . . you're trying to establish a *potential* risk that would tell you whether or not you need to have a concern in the community So for medical management purposes, one wants to understand what the risk *could have been as high as*.

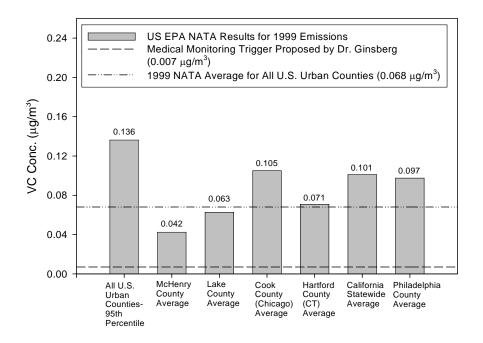
Ginsberg Dep. II at 190-91 (emphasis added). He said he used the "high" scenario because he believed, contrary to fact, that it (rather than the Zannetti team's misnamed "low" scenario) was based on average well readings:

[T]he quote, unquote, real risk, which is the exposure and risk that people were actually subjected to, could equally well be the high risk and not some average between the two, because the way the high risk was calculated, it's not as if they took one cherry-picked high end number and projected that automatically to all

people. There were a number of wells which average concentrations were taken from

Ginsberg Dep. II at 192-93 (emphasis added). But, as discussed in Part III.B of this omnibus motion, "cherry pick" is exactly what the Zannetti team did when they created the "high" scenario. Dr. Oberdorfer only used average concentrations in creating the "low" scenario — the scenario that Dr. Ginsberg ignored.

Dr. Ginsberg says that his 0.127 μg/m³ high estimate of vinyl chloride concentration is "above national estimates of vinyl chloride in census tracts across the country," which, he says, average 0.007 μg/m³. Ginsberg Report at 37. Dr. Ginsberg also asserts that any exposure above this purported 0.007 μg/m³ background level would warrant medical monitoring for brain cancer. Ginsberg Dep. II at 293-294. He bases these assertions on the U.S. Environmental Protection Agency's preliminary and incomplete National Air Toxics Assessment (NATA) survey from 1996. Ginsberg Report at 37. Dr. Ginsberg never mentions that the EPA conducted a completely new NATA survey in 1999, based on an improved methodology that included twice as many emission sources as its 1996 survey. *See* Valberg Report (Battle Aff., Vol. II) at 3, 16. As the chart below from page 18 of Dr. Valberg's report depicts, this 1999 survey reports average national background levels of vinyl chloride of approximately 0.07 μg/m³ — 10 times higher than were reported in 1996. Valberg Report at 16-18. The 1999 survey also reports that in Cook County, Illinois, which includes Chicago, background levels are greater than 0.1 μg/m³; and in McHenry County, where McCullom Lake Village is located, they are 0.042 μg/m³.



Notably, in the Zannetti team's misnamed "low" scenario (really an "average" scenario), outdoor concentrations of vinyl chloride in McCullom Lake Village throughout the 25-year period on which Dr. Ginsberg focuses (1978 to 2002) — indeed, throughout the entire class period that plaintiffs propose (1968 to 2002) — were significantly *below* background levels reported in the 1999 survey. Similarly, had Dr. Ginsberg calculated his outdoor exposure estimate using the Zannetti team's "low" scenario, rather than the cherry-picked "high" scenario, his outdoor air estimate would have been below these background levels. Indeed, it would have been 0.011 µg/m³, ten times lower than the 0.127 µg/m³ figure upon which he relies on in his report. *See* Valberg Report at 16.

Indoor exposure. Dr. Ginsberg theorizes that indoor contamination in the purpleplume area occurred when area residents used their well water to take showers, wash dishes, and engage in other household activities. Using the calculations from Dr. Andrews, Dr. Ginsberg says that an individual living in a house above the hypothetical plume for the entire 25-year time period between 1978 and 2002 would have experienced an average concentration of vinyl chloride in his or her indoor air of 1.81 μ g/m³. That is less than one part per billion.⁶

As explained further below, Dr. Ginsberg calculated this exposure figure based on Dr. Andrews' estimates of the amount of vinyl chloride that supposedly entered Village wells in the purple plume area. To perform this calculation, Dr. Ginsberg used an outdated formula based on artificial assumptions that the toxicological community now universally rejects. As a result, even if Andrews' purple-plume model were accepted as sound, Dr. Ginsberg's $1.81 \,\mu\text{g/m}^3$ purported indoor air exposure estimate is overstated by a factor of more than ten. Valberg Report at 13.

Dr. Ginsberg adds his calculated indoor air concentration of 1.81 μ g/m³ to his calculated outdoor concentration of 0.127 μ g/m³ to obtain a purported total exposure of approximately 1.94 μ g/m³ for residents who lived directly above Dr. Andrews' hypothetical purple plume for the entire 25-year period from 1978 to 2002. *See* Ginsberg Report at 34.

b. The Risk Estimate

There is no scientific evidence that exposure to vinyl chloride increases the risk for brain cancer. *See* Marsh Report at ¶¶ 44-60; Bigner Supp. Report at 9; Valberg Report at 20-22 (all attached to Battle Aff., Vol. II). Therefore, to create a risk estimate, Dr. Ginsberg relied on data about vinyl-chloride-induced liver angiosarcoma risk. Both EPA and the California Environmental Protection Agency ("CalEPA") have estimated a "unit risk" for liver angiosarcoma

^{6.} See Valberg Report at 21. As Dr. Valberg explains, one part per billion is the equivalent of about 1 second in a span of 32 years, or the weight of single human hair compared to a 3-ton SUV. *Id* at 21 n.8.

based on a lifetime exposure to vinyl chloride in concentrations of 1 μ g/m³. The EPA's estimate for adults is 4.4×10^{-6} (that is, 0.0000044) per μ g/m³. This means that if a million adults were continuously exposed over their lifetime to 1 μ g/m³ of vinyl chloride, one would expect to observe 4.4 more liver angiosarcomas in those million individuals than would otherwise occur. Ginsberg Report at 29; *see also* Valberg Report at 31. By contrast, CalEPA estimates a higher unit risk — 7.8×10^{-5} (that is, 0.000078) per μ g/m³ — meaning that, in CalEPA's view, if 100,000 people were continuously exposed for their lifetime to 1 μ g/m³ of vinyl chloride, one would expect to observe 7.8 additional liver angiosarcomas in those 100,000 people. Dr. Ginsberg used both of these statistics in his estimate.

The EPA and CalEPA unit risk factors are for liver angiosarcoma. There is no comparable number for a link between vinyl chloride and *brain* cancer because no such link has been observed. So Dr. Ginsberg proceeded to "adjust" the unit risk factors for liver angiosarcoma to try to make them apply to brain cancer. He did this by dividing these unit risk factors by 2.6.

The source of Dr. Ginsberg's 2.6 "adjustment" factor was a 1981 study by Dr. C. Maltoni of rats exposed to vinyl chloride in air. Ginsberg Report at 30. In that study, rats exposed to very high doses of vinyl chloride (from 6.4 to 76.8 *million* µg/m³) developed neuroblastomas, but those exposed to doses under 1.28 million µg/m³ did not. Valberg Report at 23; *see also* Maltoni, *et al.*, Carcinogenicity Bioassays of Vinyl Chloride Monomer: A Model of Risk Assessment on an Experimental Basis, Environmental Health Perspectives 41: 3-29 (1981)

^{7.} Dr. Ginsberg expresses this "unit risk" with a slightly different notation — "4.4E-6/ugm3." *See* Ginsberg Report at 29. This is just a different way of writing the same number.

("Maltoni Study") at 12 (Battle Aff., Vol. IV, tab 7). The rats did develop liver angiosarcomas at the lower concentrations, however. Valberg Report at 22; *see also* Maltoni Study at 12.

None of the tumors observed by Maltoni were of glial-cell origin, the types of brain tumors at issue in this case. Valberg Report at 22. The neuroblastomas that showed up when the rats were exposed to high doses were all of neural-cell origin, so subsequent researchers have suggested that they were not primary brain tumors, but instead developed first in the rats' nasal cavities and then spread to the brains. *Id.* at 23.

Despite these differences, because Maltoni's study had produced 2.6 liver angiosarcomas for every neuroblastoma, Dr. Ginsberg opined that exposure to vinyl chloride at the levels he theorized for McCullom Lake Village would lead to the same ratio of the two types of cancer there, thus allowing calculation of a unit risk factor for brain cancer by dividing the EPA and CalEPA factors for liver angiosarcoma by 2.6.

Dr. Ginsberg concedes that no other toxicologist has ever endorsed such an "adjustment":

[M]ost people aren't trying to extrapolate from one organ to another the way we are here. So what we're doing is an application, an extension of the bioassay data or the epidemiology data from one target organ to another target organ that other researchers or other applications that I'm not quite aware of that other people may have done it this way, but I'm not aware that this is something that other people commonly need to do.

Ginsberg Dep. II at 311-12 (emphasis added). Dr. Ginsberg added: "I don't have a citation that shows other people doing that [attempting to convert an established risk for one organ type into a hypothetical risk for another organ type], if that's what you're looking for." *Id*.

By dividing the EPA and CalEPA unit risk factors for liver angiosarcoma by 2.6, Dr. Ginsberg came up with unit risk factors for brain cancer based on a lifetime exposure to 1 $\mu g/m^3$ of vinyl chloride. He then multiplied that number by the exposure level he had calculated for the purple-plume houses — 1.94 $\mu g/m^3$ — and then adjusted further to account for his assumption that the exposure in the Village would be for 25 years, rather than for a lifetime. His ultimate conclusion was that the risk of brain cancer from vinyl chloride for Village residents on the purple plume ranged between 1.2×10^{-6} (that is, 0.0000012) per $\mu g/m^3$ ("roughly 1 per million") and 7.8×10^{-5} (that is, 0.000078) per $\mu g/m^3$ ("nearly 1 per 10,000"). Ginsberg Report at 35.

Dr. Ginsberg acknowledges that this very wide estimated range — 100-fold — of potential risk for brain cancer applies only to individuals who lived directly above Andrews' hypothetical purple plume for the entire 25-year period from 1978 to 2002. Ginsberg Dep. II at 289-90. Individuals who lived over the purple plume for only a portion of the time would have only a fraction of the alleged risk. *Id.* at 316-17. Thus, according to Dr. Ginsberg, the range of brain cancer risk for someone who lived over the plume for one year might be $\frac{1}{25}$ of the 25-year estimate — that is, somewhere between 1 per 25 million and 1 per 250,000.

Likewise, Dr. Ginsberg acknowledges that individuals living elsewhere in the Village (that is, off the purple plume) would have faced far less than the already negligible risks faced by those living directly above the plume, because these individuals would never have experienced the supposed $1.81~\mu g/m^3$ of vinyl chloride in the indoor air from household water use. Instead, they would have been exposed only to the supposed outdoor air concentration, which Dr. Ginsberg says was $0.127~\mu g/m^3$ (based solely on the Zannetti team's "high" scenario). Dr. Ginsberg admits that the brain cancer risk based on this exposure would be on the order of *1 per*

ten million. Ginsberg Dep. II at 223-24. He did not calculate a risk estimate using the Zannetti team's "low" (that is, average) scenario; but if he had, it would be at least ten times lower still, on the order of *1 per 100 million*.

2. ARGUMENT

a. Dr. Ginsberg's Exposure Assessment Is Unreliable.

Dr. Ginsberg's calculations of both the indoor air exposure $(1.81 \,\mu\text{g/m}^3)$ and the outdoor air exposure $(.127 \,\mu\text{g/m}^3)$ are unreliable and would not be endorsed by the toxicology community. Thus, Dr. Ginsberg has failed to "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho*, 526 U.S. at 152.

The first defect in his exposure assessment is his reliance on improper data from plaintiffs' other experts regarding water and air contamination levels in the Village. As discussed in Parts III.A and B of this motion, the data of Dr. Andrews and the Zannetti team is flawed in many respects, and those flaws infect Dr. Ginsberg's opinions as well and make them inadmissible.

Dr. Ginsberg compounded their errors when he based his own calculations on the "high" air concentration scenario created by the Zannetti team. The air modelers offered *two* alternative scenarios — their artificially inflated "high" and their average alternative (which they called "low") — and provided no basis upon which a toxicologist like Dr. Ginsberg, who has no air modeling experience of his own, could decide which was more appropriate for determining (in Dr. Ginsberg's words) "what the risk could be as high as." Ginsberg Dep. II at 189-91. Lacking guidance, Dr. Ginsberg picked the higher one, though he conceded that he appropriately

could have used the other one as well. *Id.* at 189-90. When asked why he picked the high one, Dr. Ginsberg said he thought it was based on averages, rather than cherry-picking. That reasoning would have led Dr. Ginsberg to select the Zannetti team's "low" scenario, which really was an average. Dr. Ginsberg thus did not even use data consistent with his own rationale.

Similarly, Dr. Ginsberg's calculation of the supposed indoor air contamination in houses above the hypothetical plume was infected with data errors, as well as fundamental lapses in accepted scientific methodology. The upshot of these errors is that even if Dr. Andrews' hypothetical plume really existed (which it does not) and even if the vinyl chloride concentrations that Dr. Andrews calculated for that plume were correct (which they are not), Dr. Ginsberg's estimate of indoor air exposure based on Dr. Andrews' model would still be overstated by more than a factor of 10. Instead of a 1.81 μ g/m³ average indoor air exposure in houses above the hypothetical plume, exposures would have been on the order of 0.18 μ g/m³. *See* Valberg Report at 13.

The bulk of this ten-fold overstatement is due to Dr. Ginsberg's use of an extremely low "mixing factor" in his calculation. This reflects his artificial assumption that air does not circulate well within a house, so that if vinyl chloride were to volatize out of household water, it would remain largely in occupied areas rather than distribute evenly throughout the house. Ginsberg Report at 33; Ginsberg Dep. II at 266-70. Although simplistic early models of indoor air circulation employed such mixing factors, toxicologists now recognize that air mixes

within a house much more quickly and completely than these models indicated, so that either a very high "mixing factor," or none at all, should be used. Valberg Report at 13.8

Dr. Ginsberg's indoor air exposure estimate is further inflated by his assumption that vinyl chloride would volatize out of the tap water and into indoor household air with an 80% efficiency. There is no support for an estimate this high. The only basis Dr. Ginsberg offered for his assumption is that vinyl chloride might volatize at a rate equal to that for another chemical, TCE, which, he says, is 80%. *See* Ginsberg Report at 33. In fact, the rate at which TCE volatizes is far lower (40% to 60%). *See* Valberg Report at 10.

These are problems with Dr. Ginsberg's calculation of an across-the-board exposure estimate. But a bigger problem is that he created an "across-the-board" estimate in the first place. He calculates an average exposure for an average person. But his opinion is offered in support of a claim on behalf of real class members. A fundamental error in his analysis therefore is that he failed to take into account variations in the exposure of those individuals. As Rohm and Haas's toxicology expert Dr. Valberg explains, even assuming plaintiffs' exposure models were accurate (which they are not), there likely would be more than a 1,000-fold variation in class members' alleged exposure. Valberg Report at 19. Indeed, no two class members ever

^{8.} The denominator in Ginsberg's indoor air calculation is the product of the "air exchange rate" and the mixing factor. Ginsberg Report at 34. The air exchange rate encourages air to circulate within the house. Thus, a lower mixing factor (such as 0.15, the very low number he uses) has the effect of *decreasing* the exchange of air and therefore *increasing* the tendency of purported vinyl chloride concentrations to remain in occupied areas. By contrast, a higher mixing factor would have the effect of decreasing concentrations in occupied areas. However, as Dr. Valberg explains in his report, the accepted approach is not to artificially limit the exchange of air within the house by using a mixing factor. *See* Valberg Report at 12-13.

could have received the same dose of vinyl chloride from household water use, or even the same *average* dose. Any supposed shower concentrations of vinyl chloride would be highly dependent on individual factors, such as the water temperature (some prefer almost scalding hot showers, others do not); the flow rate (some prefer showers with vigorous water flow, others do not); and the duration of the shower (some prefer long, leisurely showers, others do not). *See id.* at 14. Similarly, each individual's alleged dose of vinyl chloride would depend on unique facts about the volume and ventilation characteristics of his or her house, the amount of time he or she spends in the house, and the length of time he or she lived in McCullom Lake Village. *Id.* at 14-15. Dr. Ginsberg made absolutely no effort to account for this wide variation in his exposure estimates.

Dr. Ginsberg also erroneously concludes that residents of McCullom Lake Village were exposed to levels of vinyl chloride in excess of national averages. Ginsberg Report at 37. As explained above, this assertion is based on his mistaken use of the EPA's unreliable and incomplete 1996 NATA survey. The EPA's 1999 survey shows that national averages are ten times higher. Valberg Report at 16. Dr. Ginsberg never acknowledged that average outdoor air concentrations of vinyl chloride in McCullom Lake Village, even as calculated by the Zannetti team (*i.e.*, their so-called "low" scenario), are *below* background levels in McHenry County and everywhere else in the greater Chicago area according to the 1999 NATA survey. Indeed, he never even acknowledged the *existence* of the 1999 survey. Either he did not know of it, or for unstated reasons he deliberately omitted it. Either way, his assertion that average ambient air concentration in McCullom Lake Village have ever been "above national estimates of [vinyl chloride] in census tracts across the country," Ginsberg Report at 37, is unreliable and thus in-admissible.

b. Dr. Ginsberg's Risk Estimate Is Unreliable.

The crux of Dr. Ginsberg's risk calculations is his "adjustment" of the EPA and CalEPA unit risk factors for liver angiosarcomas to obtain a supposed risk for brain cancer. Dr. Ginsberg admits that his "adjustment" methodology is unheard of in toxicology. It is based on a 26-year old rat study. Even apart from the fact that the study did not involve human beings, it did not involve true brain cancers. It has no relevance to this case. The methodology used is not accepted science.

(1) There Is No Support For Dr. Ginsberg's "Risk Adjustment" Methodology.

Dr. Ginsberg's sole support for his "adjustment" of liver angiosarcoma risk estimates to create a brain cancer estimate is, he says, that the ratio of liver angiosarcomas to neuroblastomas in Maltoni's 1981 rat study was 2.6. Hence, he says that the risk of developing brain cancer from vinyl chloride must be 2.6 times less than the risk for developing liver angiosarcoma. This is exactly the kind of leap that *Daubert* precludes. "[T]here is simply too great an analytical gap between the data and the opinion proffered." *General Elec. Co.*, 522 U.S. at 146.

First, the Maltoni study dealt with rats, not humans. Dr. Ginsberg offers absolutely no basis to support his assumption that a result observed in a study of rats somehow automatically applies to humans. Dr. Ginsberg's assertion that one should treat an animal study "as relevant to the humans unless you have good strong evidence . . . to disqualify a finding as not relevant to people," Ginsberg Dep. II at 313-14, gets things completely backwards: an animal study must be presumed *ir* relevant unless there is "good strong evidence" to think it relevant, the burden of proof being placed firmly on the party wishing to rely on the study. *See, e.g., Paoli*, 35 F.3d at 743 ("in order for animal studies to be admissible to prove causation in humans, there

must be *good grounds* to extrapolate from animals to humans") (emphasis added); *Domingo v*. *T.K.*, 289 F.3d 600, 606 (9th Cir. 2002) (expert must provide "analytical support for the extrapolation from animals to humans" and "must set forth the steps used to reach the conclusion that the [animal] research is applicable"); *Bell v. Swift Adhesives, Inc.*, 804 F. Supp. 1577, 1580 (S.D. Ga. 1992) (expert "fail[ed] to specifically cite any scientific evidence to support her conclusion that the results of the animal studies are relevant to predicting the carcinogenic effects of methylene chloride on humans").

Second, the Maltoni study did not deal with true brain cancers. It dealt with neuroblastomas, cancers that affect nerve cells and can occur anywhere in the body. By contrast, the cancers that plaintiffs say occur at excess rates in the Village are oligodendrogliomas and glioblastomas, each of which affects glial cells, not nerve cells, and occur only in the brain. Valberg Report at 23. Furthermore, the evidence suggests that the neuroblastomas Maltoni observed in rats in the 1981 study were cancers that occurred in the nasal passages and spread to the brain. *Id.* So, contrary to Dr. Ginsberg's assertion, the Maltoni study does not provide any basis for inferring anything about the relative potency of vinyl chloride exposure to produce glial-cell brain tumors in humans.

Third, the neuroblastomas observed in the Maltoni study occurred only at very high doses — 2,500 to 30,000 ppm (6,400,000 to 76,800,000 $\mu g/m^3$) — millions of times greater than the 1.94 $\mu g/m^3$ Dr. Ginsberg hypothesizes for residents above Dr. Andrews' purple plume. Valberg Report at 23. Dr. Ginsberg provides no evidence for presuming that any ratio of liver angiosarcoma to neuroblastoma supposedly observed in the high does involved in the Maltoni study would hold at the extremely low doses Dr. Ginsberg projects for Village residents.

Dr. Ginsberg attempts to bolster his use of the arbitrary 2.6 "adjustment factor" by erroneously asserting that this same 2.6 ratio was observed in several human epidemiological studies involving vinyl chloride, but these epidemiological studies provide no support for this 2.6 ratio. They too involved very high doses (12.8 *million* µg/m³) and presented no statistical analysis of the data. Other studies that have looked for a link between vinyl chloride and brain cancer have failed to find it. *See* Valberg Report at 23-24.

(2) Dr. Ginsberg's Opinions Are Not Admissible Because Risk Calculations Based On Regulatory Standards Are Inherently Inflated.

Dr. Ginsberg ultimately derives his supposed one-in-a-million brain cancer risk (the low-end of his calculated range) from the EPA's unit risk factor for liver angiosarcoma, 4.4 \times 10⁻⁶ per µg/m³. Similarly, he derives his supposed 1-in-10,000 risk (the high-end of the range) from the CalEPA unit risk factor, 7.8×10^{-5} per µg/m³. Neither agency estimate attempts to capture an actual risk associated with vinyl chloride exposure. Valberg Report at 33. Rather, such government estimates are based on policy judgments that overstate actual risks. *Id.* at 33-34. As a matter of law, such agency benchmarks cannot be used as a basis for liability in a civil action. See, e.g., O'Neal v. Dep't of the Army, 852 F. Supp. 327, 333 (M.D. Pa. 1994) ("While appropriate for regulatory purposes in which the goal is to be particularly cautious, [EPA's] upper-bound estimates overstate the actual risk and, so, are inappropriate for use in determining whether medical monitoring should be instituted."); Nat'l Bank of Commerce v. Associated Milk Producers, Inc., 22 F. Supp. 2d 942, 961 (E.D. Ark. 1998) ("regulatory agencies employ a different perspective in setting 'action levels' than do courts in imposing tort liability. Establishing that the risk of causation 'is not zero' falls woefully short of the degree of proof required by *Daubert* and its progeny"), aff'd, 191 F.3d 858 (8th Cir. 1995).

In short, Dr. Ginsberg's risk calculations are inherently overstated and not based on any accepted methodology. His opinions should be excluded.

c. Dr. Ginsberg's Opinions Do Not Fit This Case.

Quite apart from all of the flaws in Dr. Ginsberg's methodology identified above, Dr. Ginsberg's opinions are not admissible because they fail *Daubert*'s "fitness" prong; they do not "logically advance[] a material aspect of the proposing party's case." *Daubert II*, 43 F.3d at 1315.

(1) Dr. Ginsberg's Opinions Do Not "Fit" Plaintiffs' Claim For Medical Monitoring.

At the end of the day, Dr. Ginsberg simply fails to identify any significant increase in the risk for brain cancer that class members supposedly face. His conclusion, flawed as it is, for people who lived above Dr. Andrews' hypothetical plume for the entire 25-year time period is that these individuals faced an increased brain-cancer risk of somewhere between 1 per million and 1 per 10,000. Even assuming this supposed range were accurate and reliable (which it is not, for all the reasons explained above), these risks simply are not significant.

To begin with, this range of risks is within the limits set by EPA regulations. *See* 40 C.F.R. § 300.430(e)(2)(i)(A)(2) ("acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10⁻⁴ [*i.e.*, one per 10,000] and 10⁻⁶ [*i.e.*, one per million]"); *see also* Valberg Report at 36-37. As a matter of law, risks falling within the EPA's acceptable exposure limits cannot be deemed significant. *Cf. In re W.R. Grace & Co.*, 355 B.R. 462, 491-93 (Bankr. D. Del. 2006) (asbestos exposure within EPA's 10⁻⁴ to 10⁻⁶ risk range "poses no unreasonable risk of harm").

Furthermore, the range of possible risks that Dr. Ginsberg purports to have calculated cannot be considered significant because these risks are too small to have any measurable effect on the expected number of brain cancers in the Village. Even if the purported high end risk of one per 10,000 applied, it is extremely unlikely that a single vinyl chloride-induced brain cancer would occur in a village of 1,000 residents, such as McCullom Lake Village, even if all were monitored for an entire lifetime. A risk is only "significant" if it is "likely to have influence or effect." *O'Neal*, 852 F. Supp. at 338 & n.8 (an increased cancer risk of 25% to 25.03% "cannot be considered 'significant,' as required by the *Paoli* test"). The risks calculated by Dr. Ginsberg fail this test.

This is all the more true when considering individuals who lived above the alleged purple plume for less than the entire 25-year period. Dr. Ginsberg says such people would face only a fraction of the already negligible risk he has calculated. Similarly, Dr. Ginsberg says that people who live elsewhere in the village had an exposure that "could have been as high as" $0.127~\mu g/m^3$. Ginsberg Dep. II at 189-91. Leaving aside that even this number is artificially inflated because it is based on the Zannetti team's "high" scenario, Dr. Ginsberg admits that this exposure would correspond to something like a 1 in 10 million risk for brain cancer. Ginsberg Dep. II at 223-24.

Dr. Ginsberg's only real attempt to argue that these miniscule risks are nevertheless significant is to fall back on the unsupportable position that *any* amount of exposure to vinyl chloride creates an excessive risk for brain cancer that requires monitoring. Dr. Ginsberg says in

^{9.} Dr. Ginsberg suggests that someone who lived above the hypothetical plume for one year would have had $\frac{1}{25}$ of the risk, *i.e.*, a risk between 1 in 25 million and 1 in 250,000. Ginsberg Dep. II at 316-17.

his report that there is "no known safe level" of exposure, Ginsberg Report at 36, and in his deposition testified that:

[F]or vinyl chloride the concern is for this type of carcinogen . . . is that any amount of exposure is important to avoid, because there is no known threshold, there is unlikely to be a threshold within reasonable limits of exposure down — even down in this range, it's unlikely for there to be a threshold such that every increment above what is just general atmospheric background, and there is a tiny bit of atmospheric background, that any increment above that is a cause for concern and is a cause for an increase in risk.

Ginsberg Dep. II at 223-24 (emphasis added).

Courts have uniformly refused to admit this "no safe level" theory because it "cannot be falsified, nor can it be validated. To the extent it has been subjected to peer review and publication, it has been rejected by the overwhelming majority of the scientific community. It has no known or potential rate of error. It is merely an hypothesis." *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 25 (D. Mass. 1995); *see also Johnston v. United States*, 597 F. Supp. 374, 393-94 (D. Kan. 1984) (rejecting the no-safe-level theory). Indeed, Dr. Ginsberg's "no-safe-level" theory "would lead to an impossible link of causation. If one exposure is sufficient for causation, there would be no way to determine which exposure caused a particular cancer since we are exposed to carcinogens to some degree in the ambient environment on a daily basis." *Wills v. Amerada Hess Corp.*, 2002 U.S. Dist. LEXIS 1546, *46 (S.D.N.Y., Jan. 31, 2002), *aff'd*, 379 F.3d 32 (2d Cir. 2004).

(2) Dr. Ginsberg's Opinions Do Not "Fit" Plaintiffs' Motion For Class Certification.

Nor do Dr. Ginsberg's opinions advance plaintiffs' request for certification of a proposed medical monitoring class. Plaintiffs say that this Court should certify the class because

"each class member was exposed beyond the minimum level necessary to pose a heightened risk," and "medical monitoring is warranted for each and every member of the Class." Pl. Repl. Br. at 54-55. But Dr. Ginsberg's testimony does not support these cavalier assertions.

First, Dr. Ginsberg never says that every class member was exposed beyond a supposed "danger point" for medical monitoring. Indeed, Dr. Ginsberg himself says that class members would have had wide variation in their purported exposure to vinyl chloride. Depending on which of the Zannetti team's scenarios is utilized, there is a 15 to 150-fold variation between the exposure supposedly experienced by someone living directly above the hypothetical purple plume and someone living elsewhere in the Village. Likewise, there is a 30-fold variation in the alleged exposure to people living above the hypothetical plume depending on what years they lived there. Valberg Report at 19.

Second, none of Dr. Ginsberg's opinions support plaintiffs' assertion that they can prove at trial that every class member needs medical monitoring. As noted above, even the purported risks that Dr. Ginsberg has calculated for individuals living directly above the alleged plume for the entire 25 years from 1978 to 2002 would not present a significantly increased risk of brain cancer. But, as already discussed, not all Village residents faced the same risk. Thus, far from supporting plaintiffs' request for class certification, Dr. Ginsberg actually refutes plaintiffs' assertion that they will show that every class member requires medical monitoring for brain cancer.

In short, Dr. Ginsberg's opinions do not "logically advance[] a material aspect of the proposing party's case," *Daubert II*, 43 F.3d at 1315, and should be excluded.

d. Dr. Ginsberg's Opinions Should Be Excluded Because He Fails To Testify To A Reasonable Degree Of Scientific Certainty Concerning The Actual Risks Class Members Supposedly Face.

An expert can only "assist[] the trier of fact" if the expert's opinions are held to a "reasonable degree of scientific certainty." *Lanza*, 537 F. Supp. at 785. Expert testimony that fails to reach this threshold is little more than "speculation and conjecture." *Id.* Such testimony provides "nothing on the record with which a factfinder can make a decision with sufficient certainty so as to make a legal judgment." *Paoli*, 35 F.3d at 751 *quoting Cohen v. Albert Einstein Medical Ctr.*, 592 A.2d 720, 723 (Pa. Super. Ct. 1991).

Nowhere in his report or deposition testimony does Dr. Ginsberg ever offer any opinion to a reasonable degree of scientific certainty concerning any class member's actual risk for brain cancer. All he has to offer is conjecture about what the risk "could be." Ginsberg Dep. II at 247-48.

First, as to individuals living directly above Dr. Andrews' hypothetical purple plume, Dr. Ginsberg says that there could be a lifetime risk for brain cancer of somewhere between 1 per million and 1 per 10,000 (provided they lived there for the entire 25-years between 1978 and 2002). Ginsberg Report at 35-36. Dr. Ginsberg makes no attempt to narrow the range any more precisely than this. Moreover, he concedes that a one-in-a-million risk is *de minimis*. Ginsberg Dep. II at 105. Thus, all Dr. Ginsberg says in the end is that the lifetime risk for individuals living directly above Dr. Andrews' hypothetical plume for the entire 25-year time period between 1978 and 2002 "could have been" *de minimis* and "could have been" higher than *de minimis*. That kind of testimony does not begin to be helpful. "[T]he trier of fact cannot make an expert's opinion *more* certain or reasonable" than the expert himself says it is. *Porter v*.

Whitehall Labs. Inc., 791 F. Supp. 1335, 1349 (S.D. Ind. 1992) (emphasis in original), aff'd, 9 F.3d 607 (7th Cir. 1993). If the expert is unwilling to "narrow [the] range of probability" to which he opines, the trier of fact cannot narrow it for him. Id.; cf. Chaney v. SmithKline Beckman Corp., 764 F.2d 527, 529-30 (8th Cir. 1985) ("The most favorable characterization of [plainitff's] proof is that there is a 20–80% probability that Tagamet causes cancer [¶] . . . Such [testimony] would invite the jury to simply guess where the causation probability fell in the 20-80% range.").

Second, for individuals who lived elsewhere in the Village, Dr. Ginsberg offers even more uncertainty. Dr. Ginsberg says the exposure of those individuals over the 25-year period from 1978 to 2002 would have been 0.127 μg/m³, an amount fifteen times less than the supposed exposure of individuals living directly above the hypothetical plume. But Dr. Ginsberg admits that he has no real basis for this 0.127 μg/m³ exposure figure. He derived it by taking a time-weighted average of the Zannetti team's "high" scenario, which he said he selected in order to see what the risk to such individuals "could have been as high as." Ginsberg Dep. II at 189-91. He conceded that he had no reasonable ground for choosing between the Zannetti team's "high" and "low" scenarios, which he said were "equally plausible." Ginsberg Dep. II at 189-94. Indeed, on his own admission, he is only "trying to establish a *potential* risk that would tell you whether or not you need to have a concern in the community." Ginsberg Dep. II at 188-91 (emphasis added). So, here again, Dr. Ginsberg is not attempting to testify to a reasonable degree of professional certainty concerning the *actual* exposure or risk these class members faced.

Furthermore, if Dr. Ginsberg had bothered to calculate a 25-year time weighted average using the "low" scenario, the result would have been approximately 0.011 ug/m3 — an exposure that is *below* background levels both in McHenry County and across the nation accord-

ing to the EPA's 1999 survey. Thus, at most Dr. Ginsberg can say that residents who did not live above Dr. Andrews' hypothetical plume "could have had" exposures above background (based on the "high" scenario) and "could have had" exposures below background (based on the "low" scenario. Again, this kind of testimony does not assist the trier of fact and should be excluded. *Cf. Chaney*, 764 F.2d at 529-30; *Porter*, 791 F. Supp. at 1349.

D. DR. SIDNEY D. FINKELSTEIN

Plaintiffs have proffered a report of Sidney D. Finkelstein, M.D., to prove that (a) there were deletions to chromosome 3 in brain tumor samples from six plaintiffs who have filed their own personal injury lawsuits against defendants in the Philadelphia Court of Common Pleas; and (b) such deletions show that such brain tumors were caused by exposure to chlorinated solvents. The report fails to meet the criteria for expert evidence under Rule 702 and *Daubert* because it is not based upon sufficient facts or data and is not the product of reliable principles and methods.

1. BACKGROUND

The best way to show the fatal deficiencies in Dr. Finkelstein's opinion is to contrast it with real science.

a. Real Science: The German Studies — VHL Gene Mutation.

Over the last 20 years, German researchers studied employees exposed to trichloroethylene in the workplace who had developed a specific kind of kidney cancer: renal cell carcinoma. The German researchers concluded that there was sufficient evidence to support an association between trichloroethylene and renal cell carcinoma and that the individuals affected bore a mutation on a portion of a specific gene — the von-Hippel Lindau ("VHL") gene — in such tumors. The VHL gene is one of many hundreds of genes on chromosome 3. Louis Report (in Battle Aff., Vol. II) at 9-10.

Numerous papers by various German researchers reported on the causal association between exposure to elevated levels of trichloroethylene in the workplace and renal cell carcinoma. The papers were published by several scientific journals, making them subject to wide peer-review scrutiny. See, e.g., Brüning, et al., Renal Cell Cancer Risk & Occupational Exposure to Trichloroethylene: Results of a Consecutive Case-Control Study in Arnsberg, Germany, Am. J. of Indus. Med. 43: 274-285 (2003) (citing Vamvakas, et al., Renal Cell Cancer Correlated with Occupational Exposure to Trichloroethylene, J. Cancer Res. Clin. Oncol. 124: 374-382 (1998)) (Def. Ex. 2); Wartenberg, et al., Trichloroethylene & Cancer: Epidemiologic Evidence, Environ. Health Perspectives 108 (Suppl. 2): 161-176 (2000) (included with Def. Ex. 2). The scientific community accepted the validity of the underlying research and the soundness of the inferences drawn. See, e.g., Brüning, Am. J. of Indus. Med. 43: 274-285 (reporting on study of workers exposed to trichloroethylene and providing history of earlier papers on topic). As a result, the association between exposure in the workplace to elevated levels of trichloroethylene and renal cell carcinoma has achieved the status of a generally accepted scientific proposition. See id.

b. Dr. Finkelstein's Opinion.

Dr. Finkelstein, whom plaintiffs have tendered as an expert in molecular pathology, developed a methodology solely for purposes of litigation that mimicked the German research to a point, but then stopped without doing the work necessary to form a reliable scientific opinion. His July 2007 report focuses on just six plaintiffs who have filed their own suits in the Philadelphia Court of Common Pleas. Dr. Finkelstein says in his report that he chose those six plaintiffs for his analysis of damage to chromosome 3 in brain cancer tissue because the six lived in locations "representative of the Village and the McCullom Lake Area as a whole." Finkelstein Report (Pl. Repl. Br., Ex. L) at 6. Dr. Finkelstein has since admitted that this statement is false: (a) counsel for plaintiffs, not Dr. Finkelstein, selected the plaintiffs to be analyzed; (b) Dr.

Finkelstein had no say as to which plaintiffs were included in his analysis, and which were excluded; (c) Dr. Finkelstein did not even know what criteria had been used by counsel for plaintiffs in selecting those to be included in his analysis. Finkelstein Dep. at 116-17.

The analysis that Dr. Finkelstein did with respect to the six plaintiffs was materially different from the type that had been done by the German researchers. First, unlike the German researchers, Dr. Finkelstein looked for mutations on chromosome 3 in only those six plaintiffs, without also analyzing a control group of persons with brain cancer who had not been exposed to chlorinated solvents. *Compare* Finkelstein Dep. at 198 ("The internal control was the patient's [non-cancerous] tissue.") with Brauch, et al., VHL Mutations in Renal Cell Cancer:

Does Occupational Exposure to Trichloroethylene Make a Difference? TOXICOLOGY LETTERS 151 (2004): 301-310 at 302 (identifying control group as non-exposed renal cell carcinoma patients against which findings were measured) (Battle Aff., Vol. IV, tab 1). A control group of persons who had not been exposed would provide a means of comparing mutations in the six plaintiffs to those of unexposed persons, and would rule out the possibility that the mutations were unrelated to exposure. Louis Report at 4. Without a control group, however, any opinion that any mutations were caused by the exposure could be nothing more than speculation, since there could be no showing that the same mutations were not observed in unexposed persons. *Id*.

Second, Dr. Finkelstein failed to rule out other possible causes of mutations in the six plaintiffs, besides exposure to chlorinated solvents. In particular, he failed to determine whether any of the tissue samples he analyzed from the six had been taken after the plaintiffs had received radiation or chemotherapy treatments — a critical failure since, as Dr. Finkelstein acknowledged, radiation and chemotherapy treatments are known causes of the types of mutations at issue here. *See* Finkelstein Dep. at 131-32, 245.

Third, and perhaps most important, Dr. Finkelstein's detections of deletions on chromosome 3 is scientifically meaningless. When Dr. Finkelstein analyzed the tissue samples from the six plaintiffs, he looked at specific genes in chromosome 3 in a search for mutations, just as the German researchers did. In particular, he analyzed the VHL gene, as well as the topoisomerase and retinoic acid receptor-b genes. *Id.* at 60-63, 75-76, 81, 88-89, 102. This analysis failed to reveal anything remarkable as to any of the six plaintiffs: *none* of the specific genes on chromosome 3 that Dr. Finkelstein examined had any mutations. *Id.* Dr. Finkelstein did not bother to mention this fact in his report.

Beyond that, rather than looking for mutations on specific genes, Dr. Finkelstein just looked for mutations on 16 different sites on the 2 arms of chromosome 3 and found deletions or mutations at some of those sites for some of the plaintiffs. But since each of his 16 sites contained many genes, Dr. Finkelstein could not identify the specific gene that had the deletion or mutation. *Id.* at 201. Nor could he say there was a deletion or mutation on the same gene for any two of the six plaintiffs he analyzed. *Id.* at 202, 212.

Dr. Finkelstein decided that if he found 4 or more deletions in chromosome 3, then the deletions must have been caused by chlorinated solvents. *Id.* at 209-11. He made up this system for scoring mutations. It is not supported by any article or published text. *Id.*

Apart from his analysis of brain tissue, Dr. Finkelstein also examined liver tissue samples from plaintiff Irene Suchor, who has cirrhosis, and found damage "at position 310 in the mtDNA sequence." Finkelstein Report at 19. Dr. Finkelstein *assumed* Ms. Suchor had not abused alcohol, and, on that assumption, decided it was "reasonable to conclude that toxin exposure is the etiologic cause for liver cirrhosis." *Id.* Dr. Finkelstein never reviewed plaintiff

Suchor's medical records or made any independent inquiry as to her alcohol consumption history. *See* Finkelstein Dep. at 85-86, 95-96. Moreover, Dr. Finkelstein conceded that the cirrhotic tissue taken from Ms. Suchor was consistent with alcohol abuse. *Id.* at 93-95. He ruled out such abuse as a possible cause only because he assumed there was none. Finkelstein Report at 19.¹⁰

2. Argument

a. Dr. Finkelstein's Opinions Are Not Based Upon Sufficient Facts or Data.

There are a number of deficiencies in the facts and data from which Dr. Finkelstein attempts to make a quantum leap to his for-litigation-only conclusion. As a result, his procedures and methods are so unreliable that his opinion should be excluded.

First, Dr. Finkelstein's data is insufficient because he failed to analyze a control group of persons with brain cancer who had not been exposed to chlorinated solvents with which to compare his findings from the six plaintiffs. Louis Report at 4; Bigner Supp. Report at 5-6. Supposed findings from a study group without regard to those of a control group are meaningless, particularly when submitted to a court in an expert report. See United States v. Tranowski, 659 F.2d 750, 757 (7th Cir. 1981) ("the trial court should not be used as a testing ground for theories supported neither by prior control experiments nor by calculations with indicia of reliability").

Discovery is ongoing in the *Suchor* case and not all medical records have yet been produced to defendants.

Dr. Finkelstein seeks to sidestep this deficiency by claiming that "chromosome 3 deletions have not been reported for sporadic brain cancers in the peer-reviewed literature." thereby implying that a control group of "sporadic" brain cancer patients would not reveal similar mutations. See Finkelstein Report at 5. But Dr. Finkelstein knows better. Numerous studies of sporadic brain tumors having nothing to do with alleged exposure to chlorinated solvents have reported deletions on chromosome 3 — including a study authored by Dr. Finkelstein himself. See Mohan, Finkelstein, et al., Microdissection and Genotyping of Gliomas: Therapeutic and Prognostic Considerations, MODERN PATHOLOGY 17: 1346-58 (2004) (analyzing allelic losses on chromosome 3p) (Battle Aff., Vol. IV, tab 9); Srivastava et al., Frequent Loss of Heterozygosity Encompassing the hMLH1 Locus in Low Grade Astrocytic Tumors, J. NEUROONCOLOGY 81: 249-55 (2007) (Battle Aff., Vol. IV, tab 10); Zakrzewska et al., Diverse Molecular Pattern in Bihemispheric Glioblastoma (Butterfly Glioma) in a 16-Year-Old Boy, CANCER GENETICS & CY-TOGENETICS 125: 125-30 (2007) (included with Battle Aff., Vol. IV, tab 10); von Deimling et al., Comprehensive Allelotype and Genetic Analysis of 466 Human Nervous System Tumors, J. OF NEUROPATHOLOGY & EXPERIMENTAL NEUROLOGY 59: 544-58 (June 2000) (included with Battle Aff., Vol. IV, tab 10); see also Louis Report at 4-7 (collecting literature that reports on loss of chromosome 3 in sporadic cases of brain cancer); Bigner Supp. Report at 5-6 (same). So, Dr. Finkelstein knew that analyzing a real control group would disprove the proposition he was so eager to espouse.

Dr. Finkelstein says he compared chromosome 3 from the brain cancer tissue of each of the six plaintiffs with chromosome 3 from unaffected tissue of each such plaintiff.

Finkelstein Dep. at 175-76, 198-99. But that is not comparison to a control group. That does nothing more than establish the obvious: cells affected by cancer are likely to exhibit mutations

and deletions, whereas unaffected cells likely will not. To reach a meaningful conclusion, one must compare (a) findings in brain cancer patients who were exposed to chlorinated solvents (the study group), with (b) findings in brain cancer patients who were not exposed (the control group). Louis Report at 4; Bigner Supp. Report at 5-6. Indeed, the use of a control measure is critically important to ensuring the reliability of any scientific or technical experiment. *Estate of Kenneth Griffin v. Hickson*, 2002 U.S. DIST. LEXIS 8568, at *16 n.9 (E.D. Pa. May 9, 2002). Dr. Finkelstein never did that. Finkelstein Dep. at 247-48.

Indeed, Dr. Finkelstein's claim that he followed well-established pathology principles by allowing his opinions "to flow from an objective examination of tissue specimens" is flatly contradicted by his conclusion that Suchor's liver cirrhosis was caused by chemical exposure. Finkelstein Report at 7, 19, 23. As Dr. Finkelstein admitted, the damage he saw on Suchor's liver tissue was consistent with that of individuals with alcohol-induced cirrhosis. Finkelstein Dep. at 85-86, 95-96. Yet he disregarded those findings in favor of adopting his own unsupported assumption.

Second, Dr. Finkelstein does not know whether the tissue samples from the six plaintiffs he analyzed were taken before or after the plaintiffs received radiation or chemotherapy treatments. Finkelstein Dep. 131-132, 245. That is a critical unknown since, as Dr. Finkelstein acknowledged, radiation and chemotherapy treatments can cause the type of deletions and mutations he observed. *Id.* at 131.

Third, by his own admission, Dr. Finkelstein cannot say at what gene(s) the deletions he observed took place. The whole of chromosome 3 has, by Dr. Finkelstein's own estimation, "many hundreds" of genes. Finkelstein Dep. at 212; *see also id.* at 204-06 (admitting that

"[w]e interrogated only a small portions of what is chromosome 3"). As Dr. Finkelstein acknowledged, all he determined was that there were deletions in certain segments of chromosome 3, with each segment having "any number of genes, anywhere from three to four to even as much as twenty." *Id.* at 201-02. He did not undertake to make a gene-specific determination because it would take more "effort, time and resources" than he was willing to commit to this assignment. *Id.* at 201. He therefore does not even know if the same gene-specific site was damaged as to any two of the six plaintiffs he analyzed. *Id.* at 202, 212.

This is a major gap in his report. Genes are contained in the chromosomes in the cell nucleus and mitochondria. *See* THE MERCK MANUAL FOR HEALTHCARE PROFESSIONALS, at 2698 (18th ed. 2006) (Battle Aff., Vol. IV, tab 8). Radiation, for example (one of the two established causes of human brain cancer), 11 contributes to the development of cancer by triggering changes in a cell's *genes*. It thus is mutation of specific genes, *not* a chromosome as a whole, that causes the uncontrolled growth of cells that leads to the formation of tumors. *See id.* at 1143-46; Louis Report at 10-11.

The absence of such gene-specific data renders insufficient for purposes of Rule 702 the facts and data upon which Dr. Finkelstein based his conclusions. There is an enormous difference between (a) finding a mutation to a specific gene (actually a few specific *portions* of the VHL gene in the German research), and (b) saying, as Dr. Finkelstein does, that there are deletions somewhere on the alleles of chromosome 3, which contains "many hundreds" of genes. Finkelstein Dep. at 212; Bigner Supp. Report at 10-11. There is simply no sound scientific sup-

^{11.} Hereditary syndromes are the other established cause of brain cancer.

port for the notion that damage anywhere on chromosome 3 (or 4 or 5, etc.), rather than to a specific gene on that chromosome, is sufficient to support the inference that some chemical caused the mutation. Dr. Finkelstein himself concedes as much, admitting that (a) there is no generally accepted scientific proposition that deletions found somewhere (anywhere) on one of the arms of chromosome 3 prove that the brain cancer was caused by exposure to chlorinated solvents or any other chemical, and (b) there is not a single article or text anywhere suggesting such an association. Finkelstein Dep. at 195-96, 237-38. Indeed, the German literature to which Dr. Finkelstein referred focused narrowly on an association between trichloroethylene and renal cell cancer, not chlorinated solvents in general and not other organs. *See Brauch* (tab 1).

Although not mentioned in his report, it turns out that Dr. Finkelstein did actually look at several genes on chromosome 3 in the brain tissue samples he analyzed in a search for gene-specific mutations. The result: *he did not find any*. Finkelstein Dep. at 60-63, 75-76, 81, 88-89, 102.

b. Dr. Finkelstein's Opinions are Not Based Upon Reliable Principles and Methods.

An expert's opinion "must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." *Paoli*, 35 F.3d at 742. Dr. Finkelstein's opinions do not come close to meeting this fundamental requirement.

The factors cited above to show that Dr. Finkelstein's opinions were not based upon sufficient facts and data also show that his principles and methods are not reliable:

- (a) Dr. Finkelstein failed to create a control group (of brain cancers in persons not alleged to have been exposed to chlorinated solvents) against which he might compare his "findings" from the six plaintiffs. Louis Report at 4, 8;
- (b) Dr. Finkelstein does not know whether the tissue samples from the six plaintiffs were taken after chemotherapy or radiation treatment, either of which can itself cause deletions and mutations; and
- (c) Dr. Finkelstein's work was insufficient to identify the specific gene that bore the mutations, and so he cannot even say that any two of the six plaintiffs analyzed had deletions from the same gene. Louis Report at 10-11; Bigner Supp. Report at 10.

* * *

But there is much more or, perhaps more accurately, much less to Dr. Finkelstein's opinions.

First, there is **no** scientific basis for Dr. Finkelstein's core assertion: that deletions from the arms of chromosome 3 mean that the cancer was caused by exposure to chlorinated solvents. Dr. Finkelstein started with the work of the German researchers, described above, that established a link between exposure to elevated levels of trichloroethylene and renal cell cancer by showing damage to a portion of the VHL gene, which is one of many hundreds of genes on chromosome 3. Finkelstein Dep. at 212. From that narrowly focused study, Dr. Finkelstein — and Dr. Finkelstein alone — jumped to the conclusion that if he found damage somewhere on chromosome 3, that was enough to attribute plaintiff's brain cancer to exposure to chlorinated solvents. Dr. Finkelstein testified:

- Q. The German article concerns renal cell cancer where there is damage shown to a specific portion of the VHL gene; correct?
- A. Yes; correct.
- Q. So we have the record clear, if you put that article aside, do you know of any article in the whole wide world that says that if you find mutational changes on chromosome 3 and the patient has brain cancer, that is a sign that the brain cancer is due to chemical exposure?

A. No.

Id. at 195-96 (emphasis added.) Thus, Dr. Finkelstein can point to no body of "widely accepted scientific knowledge" that supports his view. *Kannakeril v. Terminex Int'l Inc.*, 128 F.3d 802, 809 (3d Cir. 1997). On the contrary, he concedes that his conclusions are shared by no other scientist. *See* Finkelstein Dep. at 195-96, 237-38; *see also* Louis Report at 11; Bigner Supp. Report at 2. In short, there is a significant "analytical gap between the data and the opinion proffered." *General Elec. Co.*, 522 U.S. at 146. This disconnect makes Dr. Finkelstein's opinion inherently unreliable. *See Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 474-75 (M.D.N.C. 2006).

Second, Dr. Finkelstein simply made up — literally — his scoring system for determining whether the deletions or mutations to chromosome 3 are attributable to exposure to chlorinated solvents. Dr. Finkelstein testified that if he sees four or more mutations on chromosome 3, he concludes that the tumor is "indicative of genotoxic *chemical* exposure damage." Finkelstein Dep. at 209-11 (emphasis added). No article or text supports this scoring system, *id*. — which is not surprising since no article or text supports Dr. Finkelstein's idiosyncratic view that deletions to the alleles of chromosome 3 are associated with exposure to chlorinated sol-

vents. *Id.* at 195-96, 237-38. Dr. Finkelstein conceded that he knows nobody anywhere who agrees with him:

- Q. So do I have it right then that if you find four mutations, then you say this patient's brain cancer is due to exposure to chemicals. If it's less than that, we can't draw that conclusion; is that right?
- A. Yes.
- Q. Do you know anywhere else in the whole wide world where anybody has said that —
- A. No.
- Q. other than you here today?
- A. No.

Finkelstein Dep. at 211 (emphasis added).

Indeed, Dr. Finkelstein embraces his made-up scoring system while rejecting the Bradford-Hill criteria as useless for determining whether the six plaintiffs' brain tumors were caused by chlorinated solvents. But unlike Dr. Finkelstein's novel scoring method, the Bradford-Hill criteria, which "were developed as a means of interpreting *an established association* based on a body of epidemiologic research for the purpose of trying to judge whether the observed association reflects a causal relation between an exposure and disease," *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 514 (W.D. Pa. 2003), are "the most famous method" for evaluating whether pathogens cause human disease. *Gannon v. United States*, 2007 U.S. Dist. LEXIS 52051 at *24-*25 (E.D. Pa., July 17, 2007). Dr. Finkelstein's rejection of the Bradford-Hill criteria in favor of his own novel theory clearly runs counter to established science. Moreover, it is

obvious that it would be futile to apply the Bradford-Hill criteria to Dr. Finkelstein's "findings" in this case: none of them would be satisfied. Bigner Supp. Report at 6-7.

As with the rest of his opinions, Dr. Finkelstein has not prepared any manuscript or article about his work in this litigation that would permit his peers in the scientific community to comment and critique his "findings." Id. at 193. At most, Dr. Finkelstein relies on an abstract — a one-paragraph summary presented in a poster at a meeting of the Society of Toxicology, and a far cry from a peer-reviewed publication — as his one and only effort to present his novel theory to the rest of the scientific community. And that abstract and poster address only exposure to trichloroethylene, which Dr. Finkelstein claimed was the cause of colon cancer, bladder cancer, lung squamous cell cancer and renal cell cancer in certain subjects. See Finkelstein, et al., Abstract and Poster: Dynamic Mutational Fingerprint of Acquired Damage in Cancers from Subjects Exposed to Trichloroethylene, Soc'y OF TOXICOLOGY ANNUAL MTG. (2006) (Battle Aff., Vol. IV, tab 4). Notably, Dr. Finkelstein examined the same individual genes in the cases that he described in his abstract as he did here. See id. While he found mutations on the genes he examined in those cases, he found none in the six plaintiffs he examined for his report in this case. Moreover, the 5 subjects that were discussed in Dr. Finkelstein's poster reportedly had mutations in the same chromosomal area, whereas the plaintiffs he examined here had no such commonality. Dr. Finkelstein's opinions therefore do not come close to satisfying the requirements of Rule 702 and Daubert.

Dr. Finkelstein's flawed approach is further undermined by the fact that it was developed solely for litigation purposes. Finkelstein Dep. at 43-44. He has done no independent study of chlorinated solvents as a possible cause of mutations on chromosome 3 apart from his work in (a) this case, (b) other lawsuits involving a Rohm and Haas facility in Spring House,

Pennsylvania, that were brought by counsel for plaintiffs in this case, and (c) a group of cases pending in the Court of Common Pleas of Cambria County where the plaintiffs claimed that exposure to trichloroethylene caused a variety of medical problems (including cancers of the kidney, bladder, lung, and prostate, and anosmia (loss of the sense of smell)). Dr. Finkelstein apparently passed a perfunctory *Frye* challenge (in which he was not even cross-examined) in the Court of Common Pleas of Cambria County. But this Court should not rely on that ruling on a rather skimpy record in determining whether his opinion here is scientifically reliable. *Id.* It clearly is not. Indeed, Dr. Finkelstein's method has never been used by Dr. Finkelstein outside the litigation context. *Id.* at 43-44, 57, 247-49. In fact, it has never been used by anybody else in any context. *Id.* at 43-44.

Dr. Finkelstein developed his opinions solely for the purpose of testifying; they did not grow "naturally and directly" out of independent research. *Daubert II*, 43 F.3d at 1317; *see also Marmo v. IBP, Inc.*, 360 F. Supp. 2d 1019, 1022 (D. Neb. 2005) (excluding toxicologist's testimony and report where "her opinions were developed specifically for purposes of this litigation"). Because Dr. Finkelstein has never performed any objective and independent research as to the proposition at issue, his opinions fall far short of "important objective proof that the research comports with the dictates of good science." *Daubert II*, 43 F.3d at 1317. Dr. Finkelstein's conclusions therefore are inherently unreliable.

E. DR. RICHARD NEUGEBAUER

1. BACKGROUND

Plaintiffs offer the opinions of epidemiologist Richard Neugebauer in a flawed attempt to show that the rates of two types of brain cancer in four "target areas" within and around McCullom Lake Village are higher than expected. In support of that conclusion, Dr. Neugebauer purports to have conducted two different "studies" — one an "ecologic study" and the other what he calls a "modeled cohort study." But neither of these analyses is a reliable study of brain cancer rates at all.

As Dr. Neugebauer himself admitted, an "ecologic study" is inherently preliminary: It is a study of populations, not individuals, typically based on review of readily available health statistics rather than the individualized data used in a more reliable and comprehensive "cohort study." *See* Federal Judicial Center, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (2d ed. 2000) (Battle Aff., Vol. IV, tab 3), at 391. And as Dr. Neugebauer also admitted, the ecologic study he has done so far uses a methodology he has invented for this case. Neugebauer Dep. at 150-53. It is at best no more than a crude, preliminary review, providing no basis for a conclusion that cancer rates in McCullom Lake Village are elevated. Marsh Report at ¶ 3. And his so-called "modeled cohort study" is not a cohort study at all, but rather just another version of a preliminary, ecologic study (also using a methodology invented by Dr. Neugebauer for this case), equally useless in determining whether there is an excess of brain cancers here. *Id.* at ¶¶ 12-20. What's more, even the preliminary reviews Dr. Neugebauer *has* conducted so far are so riddled with errors and outcome-driven assumptions that they provide no basis for the proposed *future* cohort study he says he will one day conduct (but has not so far) to determine whether the

rates of these types of brain cancers are elevated at all in McCullom Lake Village. *Id.* at ¶¶ 20-43.

Yet, based on nothing more than these two preliminary, inconclusive and flawed studies, Dr. Neugebauer claims to opine, "to a reasonable degree of epidemiological and scientific certain[ty]," that (1) "there is an elevated brain cancer rate" in McCullom Lake Village, (2) "there is evidence of a dose response relationship between increasing proximity to contaminated areas and excess brain cancer cases," and (3) the alleged excess of brain cancers is "more likely [than] not related to the known exposures to the chemicals" allegedly released from facilities owned and operated by Morton (and later by Rohm and Haas) and Modine. Neugebauer Report (Pl. Repl. Br., Ex. K) at 7-8. Dr. Neugebauer has no scientifically sound basis for these conclusions. Accordingly, plaintiffs should be precluded from offering Dr. Neugebauer's testimony at any hearing in this matter, including the hearing on plaintiffs' motion for class certification.

2. ARGUMENT

Because Dr. Neugebauer has made no attempt to "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field," *Kumho*, 526 U.S. at 152, the Court should exclude his opinions and bar him from testifying in support of plaintiffs' motion for class certification. Courts have not hesitated to reject expert testimony based on "assumptions [that] are epidemiologically unsound." *Padgett v. United States*, 553 F. Supp. 794, 801 (W.D. Tex. 1982) ("[A]lthough [plaintiff's epidemiology] calculations are beyond reproach, the assumptions underlying his calculations are riddled with error, and thus his conclusions are not credible."). Dr. Neugebauer's opinions are not based on sufficient facts or

data; nor are his methodologies reliable or appropriately applied to the facts of this case. Dr. Neugebauer's opinions flunk the Rule 702 test.

a. Dr. Neugebauer's "Ecologic" Study Rests On An Ill-Conceived Methodology And Fictional Assumptions.

Dr. Neugebauer's first attempt to support his claim that there is a cancer cluster in McCullom Lake Village is an "ecologic" study focusing on four "target areas" south of the defendants' plant. *See* Neugebauer Report at 8. An ecologic study is a *preliminary* study based on information about groups, not individuals. Neugebauer Dep. I at 117-18; Marsh Report at ¶¶ 13-17. It is not the kind of study on which epidemiologists base actual conclusions as to the existence or non-existence of a cancer cluster. Rather, the reason an epidemiologist does an ecologic study is to see whether there is enough information to suggest it would be worthwhile to pursue a more detailed, involved "cohort study" that takes into account individual factors such as race, gender, age, employment history, residential history, medical history, relevant exposures, lifestyle choices, and so on. Neugebauer Dep. at 120-21; Buffler Dep. at 215-16. Only a true cohort study can provide reliable information as to whether there is an excess of a disease in a given population. Marsh Report at ¶¶ 24-26.

Thus, even if it were not deeply flawed, the utility of Dr. Neugebauer's ecologic analysis would at best be extremely limited: Under the very best of circumstances, it would tell us only whether further study is warranted. Indeed, notwithstanding his statement that he has a "reasonable degree" of scientific certainty that "there is an elevated brain cancer rate" in the Village (Neugebauer Report at 7-8), what Dr. Neugebauer really concludes is just that further study is warranted. But Dr. Neugebauer's ecologic study methodology *is* deeply flawed, and so it tells

us neither whether the brain cancer rate is elevated nor whether there is any reasoned basis for pursuing a more detailed study.

b. Dr. Neugebauer Admits That No Practicing Epidemiologist Has Ever Tried To Do An "Ecologic" Community Study That Includes Non-Resident Workers.

Scott Milliman, one of the individual plaintiffs with oligodendroglioma, does not and never has resided in any of Dr. Neugebauer's four "target areas" (four overlapping, increasingly smaller areas south of the Rohm and Haas plant and centering on the proposed class area of McCullom Lake Village), and so he would not normally be included in an ecologic community study of these areas. But it is crucial to Dr. Neugebauer's analysis that he find a way to include Mr. Milliman in his study. Without Mr. Milliman, Dr. Neugebauer cannot show a "cluster" of oligodendroglioma cases in any of the three "target areas" he has identified as most directly in the alleged path of exposure from the Morton/Rohm and Haas plant (Areas 2, 3 and 4). See Buffler Report (Battle Aff., Vol. II) at 3. So, to achieve that goal, Dr. Neugebauer decided to count not just residents of his target areas, but also people whose employers' places of business were located in those areas. Neugebauer Report at 9; Neugebauer Dep. at 27-30. That expansion has no basis in accepted epidemiological principles. And Dr. Neugebauer admits it. He testified during his deposition that he is not aware of a single epidemiologist anywhere who has ever tried to include non-resident workers in a community study. Neugebauer Dep. at 120-21, 150-53.

Dr. Neugebauer deviated from normal epidemiological practice so he could count

Mr. Milliman, who, it is alleged, routinely drove through the area while patrolling his route as a

deputy in the McHenry County Sheriff's Department, and filled his water jug at the Rohm and Haas plant during his shift. *See* S. Milliman Dep. at 15-24; Neugebauer Dep. at 140-43.

Even if Dr. Neugebauer's methodology of attempting to include non-resident workers in his ecologic study of McCullom Lake Village were sound (which it is not), he has failed to implement it in any reliable fashion, ignoring relevant facts and data in favor of unsupported assumptions and thereby making the number of people against whom he counts these brain cancers artificially small (and, accordingly, making the rate appear artificially inflated). Here, although Dr. Neugebauer attempts to count the number of workers by using business directories and marketing materials, his attempts are fundamentally flawed and demonstrate the futility of such an exercise. To name just a few:

- Dr. Neugebauer excludes workers at two of the larger employers in the area Rohm and Haas and Modine. The only rationale he offers for this omission that they are employees of the defendants makes no sense and is directly inconsistent with his attempts to include area workers in his calculation. Neugebauer Dep. at 205-06.
- Even though the very point of including workers in the study in the first place was to come up with some rationale for including Mr. Milliman in the study (that is, to make his denominator correspond to his numerator for his calculations of the brain cancer rates), Dr. Neugebauer *still* did not count workers employed by Mr. Milliman's employer, the McHenry County Sheriff's Department, because it did not have its address in any of Dr. Neugebauer's four target areas. Neugebauer Dep. at 147-49.
- Dr. Neugebauer made *no* attempt to count or calculate the larger category of workers to which Mr. Milliman actually belongs non-resident workers who are not employed in the target areas, but who regularly travel through the area as part of the job. Neugebauer Dep. at 147-49. This includes law enforcement workers like Mr. Milliman, as well as countless others mailmen, UPS and FedEx drivers, delivery drivers, utility workers, repairmen, plumbers, exterminators, municipal employees, sales representatives, and so on and on. Although Dr. Neugebauer assumes that the effect of this omission is minimal, *id.* at 149, he has no actual basis for saying so.

And the list goes on, including Dr. Neugebauer's failure to consider how much time workers actually spent in the area, his flawed extrapolations from one year's worth of data to the entire study period, and his unsupported assumption that the demographic makeup of the worker population would be identical to that of the residential population. Neugebauer Dep. at 216-19; *see also* Marsh Report at ¶¶ 20-21. Although Dr. Neugebauer tries to minimize the importance of these omissions, the fact is they all point inexorably to the conclusion that his "calculation" is simply unreliable. Rather than a scientific analysis, it is little more than a guess.

Because there is no reliable way to add workers to the calculus — and because the accepted protocol for a community study is to count residents and not to count non-resident employees — the only scientifically appropriate method for addressing Mr. Milliman's case would have been to exclude him from the study altogether. He would be counted in the community where he resides. Marsh Report at ¶21; Buffler Report at 2-3. The fact that Dr. Neugebauer deviated from normal epidemiologic practice only demonstrates that his analysis was outcomedriven from the start: without Milliman, there is only one oligodendroglioma case in Dr. Neugebauer's "Target Areas" 2, 3 and 4. One case is not a cluster. One case cannot even truly be considered an excess in a relatively small population like the one under investigation here: Not only are studies of such small groups of people inherently subject to great unreliability (*see* Section I.C., *infra*), but Dr. Neugebauer himself estimates that the "expected" number of brain cancers for these areas is somewhere between 0.01 and 0.74. Since there could never be a half a person with brain cancer living in the Village, neither 0 nor 1 case would be beyond Dr. Neugebauer's numbers.

c. Dr. Neugebauer Has Consciously Selected His Target Areas To Inflate His Rates.

As with his machinations to count Mr. Milliman in his analysis, Dr. Neugebauer likewise appears to have selected his four "target areas" specifically to inflate the incidence of the two types of brain cancers he claims to be studying.

Dr. Neugebauer identifies four increasingly smaller "target areas" of study—
Area 1, which is the bottom half of a 3-mile circle drawn around the Rohm and Haas plant; Area 2, which is the census tract directly south of the plant; Area 3, which is the area of air contamination alleged by plaintiffs, and Area 4, which is the narrow area of alleged air *and* groundwater contamination depicted by plaintiffs as the purple plume on their map. Counting (or, in this case, estimating) the number of people in each area supplies the *denominator* for his calculation of the Standardized Incidence Ratio (SIR), or rate of each type of brain cancer, for that group. But his *numerators* do not change dramatically. That is because the target areas overlap; so the population he is studying (the denominator) gets smaller and smaller, but the number of brain cancers he counts stays the same. This means that the rates appear to go up as he zeroes in on the alleged "cluster." But that is a fiction.

Rather than studying the entire population in a three-mile radius from the Ring-wood plant, or studying the entire county, Dr. Neugebauer has instead zeroed in on the area where the cancers are grouped, thus falling prey to the "Texas sharpshooter" fallacy in which a cowboy fires shots at the side of a barn, then draws a circle around them, and brags that he hit the bull's-eye. There is no scientific basis for drawing the target areas as Dr. Neugebauer has — and, in fact, an epidemiologist conducting a true population-based study would not have done so. Indeed, as Dr. Neugebauer admitted during his deposition, he ignored the population in the

semicircle north of the Rohm and Haas plant — conveniently, since that is a population in which none of the individual brain cancer plaintiffs reside — in analyzing Target Area 1. The only explanation he gives for doing so is that he wanted to focus on the area of greatest exposure.

Neugebauer Dep. at 197-99, 205. But this makes no sense since, even according to plaintiffs' exposure experts, many people in the southern semicircle of that three-mile radius have no exposure at all, and some in the northern semicircle do. And he assigned Mr. Milliman to Target Area 4, the area most directly in the alleged path of contamination plaintiffs claim emanated from the plant, even though there is absolutely no basis for doing so, thereby allowing him to count an additional oligodendroglioma case in each of the four target areas.

Dr. Neugebauer's failure to articulate any accepted methodology for defining his target areas undermines the reliability of his results.

d. Dr. Neugebauer Ignores Generally Accepted Tests of Statistical Significance.

"Courts have emphasized that epidemiologic proof must be statistically significant." *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 533 (W.D. Pa. 2003). But Dr. Neugebauer pooh-poohs statistical significance altogether, arguing that the conventional and generally accepted "p value" of 0.05 (that is, that there is less than a 5% likelihood that the result is due to chance) is "simply a convention without mathematical foundation." Neugebauer Report at 12. He fails to offer any alternative. Accordingly, Dr. Neugebauer offers *no* objective test by which one can measure the significance of his results. Neugebauer Dep. at 189-91.

The reason Dr. Neugebauer abandons traditional principles of statistical significance is clear: if one follows those principles, the p values for the SIRs that Neugebauer calculates for glioblastoma multiforme (the other type of cancer he reviews) fail to achieve statistical significance in three of his four proposed Target Areas. This alone renders Dr. Neugebauer's conclusions totally unreliable. But the omission of any benchmark against which to evaluate the significance of his findings is particularly egregious here because Dr. Neugebauer relies on so few cases in his analysis.

Typically, practicing epidemiologists do not conduct or report analyses involving fewer than five cases because, with numbers so small, the addition or subtraction of a single case dramatically alters the result. *See, e.g.,* Fiore, B., et al., *Public Health Response to Reports of Clusters: State Health Department Response to Disease Cluster Reports – A Protocol for Investigation*, AMER. J. EPI., 132:S14-S22 (Battle. Aff., Vol. IV, tab 5), at S16 (1990) ("Rates are not calculated for neighborhoods or subdivisions because the number of observed cancer cases is usually too small for stable rates or meaningful analysis"). Indeed, that problem is apparent when one considers what would happen if Mr. Milliman were excluded from Dr. Neugebauer's analysis — the number of oligodendrogliomas in Areas 2, 3 and 4 would drop to 1, a number that is neither a cluster nor even a true excess. Thus, Dr. Neugebauer's calculated SIRs are so unstable that epidemiologists outside the litigation arena generally would refuse to report them.

Marsh Report at ¶¶ 41-43.

e. Dr. Neugebauer's "Ecologic" Study Does Not Show a "Dose-Response" Relationship.

Dr. Neugebauer offers his opinion, it appears, as evidence of general causation—that is, as evidence that exposure to vinyl chloride in McCullom Lake Village causes brain cancer. To that end, he claims to have discovered a "dose-response" relationship between vinyl

chloride exposure and the number of cases of brain cancer in the area. But his logic on this point fails.

In a true dose-response analysis, one compares the rate of disease in a population of lower-exposed people to that in a *different* population of higher-exposed people to see if the latter is higher. Marsh Report at ¶ 39. If it is in a statistically significant way, one might be able to draw the inference that the higher the exposure, the greater the incidence of disease. But that is not what Dr. Neugebauer has done here at all. The four "target areas" he claims to compare are four *overlapping* areas, not four different groups with differing levels of exposure. In fact, if one corrects for the overlap (that is, if you do not count either the healthy people or the brain cancer cases in Area 1 that are included in Areas 2, 3 and 4, do not count the healthy people or the brain cancer cases in Area 2 that are included in Areas 3 and 4, and so on down the line), it becomes clear that there is *no* dose-response relationship: there is 1 case of oligodendroglioma in the non-overlapping part of Area 1 (the group with the least purported exposure), no such case in the non-overlapping parts of Areas 2 and 3 (the groups allegedly having intermediate levels of exposure), and 1 case in Area 4 (the area of alleged highest exposure).

Thus, Dr. Neugebauer's analysis tells us nothing at all about a dose-response relationship.

f. Dr. Neugebauer's "Modeled Cohort" Study Is Even More Deeply Flawed.

Claiming to respond to the critique offered by Dr. Patricia Buffler in her initial report in this case, Dr. Neugebauer next purports to have conducted what he calls a "modeled cohort" study, Neugebauer Report at 20, supposedly basing his study design on cohort studies of worker populations. In reality, however, "modeled cohort" is a misnomer. (Interestingly, Dr.

Neugebauer himself did not recall in his deposition that he called it that. *See* Neugebauer Dep. at 244-45.) This study is not a cohort study at all. It is simply another preliminary ecologic study, just looking at a different slice of the pie, and carries with it all the limitations and unreliability of his first ecologic study.

As noted above, a true cohort study examines individual data for each person in the cohort, including *each individual's actual* residence history, employment history, exposure history, medical history, and so on. Neugebauer Dep. at 120-21; Buffler Dep. at 215-16. Unlike an ecologic study, which typically is based on broad assumptions and generalizations about groups of people (hence its inherent lack of reliability), a cohort study requires detailed and painstaking information-gathering as to each member of the cohort — drawn either from specific, reliable documents, such as personnel records (in the case of an employee cohort), or from detailed questionnaires and interviews of the individuals in the cohort — in order to identify *all* potential risk factors. Neugebauer Dep. at 231-32, 241-43, Buffler Report at 4. Dr. Neugebauer gathered no such information here. Neugebauer Report at 22-27. Rather, the *only* risk factor Dr. Neugebauer even considered was the alleged vinyl chloride exposure plaintiffs' counsel told him about, and even then he made no attempt to consider *individual* doses or exposures.

At the end of the day, the only two differences between this study and Dr. Neugebauer's first ecologic study are that this time (1) Dr. Neugebauer does not attempt to include workers, and (2) Dr. Neugebauer attempts (but fails) to add in "person-years" for people who moved away from McCullom Lake Village. But these two changes do not convert his study from an ecologic study into something else. In short, Dr. Neugebauer's study is really just another take on the ecologic study, and carries with it all the unreliability and indefiniteness of the first study.

IV. CONCLUSION

For all of these reasons, the Court should exclude the expert reports, opinions, and testimony of Dr. Charles Andrews, Mr. J. Gregory Hill, Dr. Paolo Zannetti, Dr. June Ann Oberdorfer, Dr. Gary Ginsberg, Dr. Sidney D. Finkelstein, and Dr. Richard Neugebauer.

Respectfully submitted,

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